SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1966

No. 336

THE TOILET GOODS ASSOCIATION, INC., ET AL., PETITIONERS,

vs.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

No. 438

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL., PETITIONERS,

vs.

THE TOILET GOODS ASSOCIATION, INC., ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

INDEX

RECORD PRESS, PRINTERS, NEW YORK, N. Y., OCTOBER 24, 1966

[fol. A]

IN THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Appendix to Appellants' Brief—Filed February 9, 1966

IN THE
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
63 Civ. 3349

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.; AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.; CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO., LTD.; FABERGÉ INC.; FRANCES DENNY, INC.; THE FULLER BRUSH CO.; THE GEORGE W. LUFT CO., INC.; THE GILLETTE COMPANY; A. M. HANSEN, doing business as HOUSE OF HOLLYWOOD; HARPER METHOD, INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUSTRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABORATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN & FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, doing business as STUDIO COSMETIC CO.; MAX FACTOR & CO.; MAYBELLINE CO.; MERLE NORMAN COSMETICS, INC.; JACK B. NETHERCUTT, doing business as NETHERCUTT LABORATORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS, INC.; OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.; PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORATORIES, INC.; SHULTON, INC.; and YARDLEY OF LONDON, INC., Plaintiffs,

against

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, Defendants.

COMPLAINT—Filed November 15, 1963

First Count

Nature of Action, Parties, Jurisdiction, Venue and Authority to Bring Action.

1. This is an action for (a) a declaratory judgment that certain provisions of the regulations entitled "Part 8—Color Additives," published in the Federal Register, June 22, 1963, 28 Fed. Reg. 6439 *et seq.* (herein called "the Color Regulations"), are not in accordance with law, are in excess of the statutory jurisdiction, authority and limitations of the defendants, and are short of statutory right, and (b) for injunctive and other relief.

2. (a) The plaintiffs, other than The Toilet Goods Association, Inc. (herein called the "Association"), are engaged in the manufacture, distribution and sale in interstate and foreign commerce of cosmetics subject to the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 USC §301 *et seq.* (herein called the "Act"). The plaintiffs join as such in this one action since they assert rights to relief in respect of and arising out of the same transaction and occurrence, and questions of law and fact common to all of them will arise in the action. The plaintiffs, other than the Association, are herein collectively called "the plaintiff companies." The plaintiff companies are members of the Association, which is a nonprofit organization of cosmetic manufacturers whose members represent in excess of 90% of the annual sales of cosmetics in the United States.

[fol. B] (b) The following is the state of incorporation of each plaintiff, which is a corporation, and the principal place of business of each plaintiff:

Plaintiff	State of Incorporation	Principal Place of Business
The Toilet Goods Association, Inc.	New York (Membership Corporations Law)	1270 Avenue of the Americas, New York, New York
Anita D'Foged, Inc.	California	413 North Canon Drive, Beverly Hills, California
Avon Products, Inc.	New York	30 Rockefeller Plaza, New York, New York
Beauty Counselors, Inc.	Michigan	17108 Mack Avenue, Grosse Pointe, Michigan
Bonne Bell, Inc.	Ohio	18519 Detroit Avenue, Cleveland, Ohio
Bourjois, Inc.	New York	711 Fifth Avenue, New York, New York
Charles of the Ritz, Inc.	Delaware	11 East 58 Street, New York, New York
Chesebrough-Pond's Inc.	New York	485 Lexington Avenue, New York, New York
Christian Dior Perfumes Corp.	New York	730 Fifth Avenue, New York, New York
Clairol Incorporated	Delaware	1290 Avenue of the Americas, New York, New York
Colonial Dames Co., Ltd.	California	1060 South Vail, Montebello, California
Fabergé Inc.	New York	395 South Broad Avenue, Ridgefield, New Jersey
Frances Denney, Inc.	Pennsylvania	5935 Woodland Avenue Philadelphia, Pennsylvania

Plaintiff	State of Incorporation	Principal Place of Business
The Fuller Brush Co. ..	Connecticut	East Hartford, Connecticut
The George W. Luft Co., Inc.	New York	34-12 36th Avenue, Long Island City, New York
The Gillette Company (The Toni Company Division)	Delaware	Gillette Park, Boston, Massachusetts
A. M. Hansen, doing business as House of Hollywood		777 East Gage Avenue, Los Angeles, California
Harper Method, Inc.	New York	1233 East Main Street, Rochester, New York
Helena Rubinstein, Inc.	New York	655 Fifth Avenue, New York, New York
Helene Curtis Industries, Inc.	Illinois	4401 West North Avenue, Chicago, Illinois
Henry/Haran/Hutchings, Inc.	California	5815 Harold Way, Hollywood, California
Herbold Laboratory, Inc.	California	8008 West Third Street, Los Angeles, California
John H. Breck, Inc.	Delaware	115 Dwight Street, Springfield, Massachusetts
Kolmar Laboratories, Inc.	Delaware	Port Jervis, New York
[fol. C] Lady Lennox Company, Inc.	Tennessee	Memphis, Tennessee
Lehn & Fink Products Corporation	Delaware	445 Park Avenue, New York, New York

Plaintiff	State of Incorporation	Principal Place of Business
Arnold L. Lewis, doing business as Studio Cosmetic Co.		12232 West Olympic Boulevard, Los Angeles, California
Max Factor & Co.	Delaware	1655 North McCadden Place, Hollywood, California
Maybelline Co.	Delaware	5900 Ridge Avenue, Chicago, Illinois
Merle Norman Cosmetics, Inc.	Nevada	9130 Bellanca Avenue, Los Angeles, California
Jack B. Nethercutt, doing business as Nethercutt Laboratories		9130 Bellanca Avenue, Los Angeles, California
Neutrogena Corp. (Natone Company Division)	California	Los Angeles, California
Nutrilite Products, Inc.	California	5600 Beach Boulevard, Buena Park, California
Old 97 Company	Florida	Tampa, Florida
Private Label Cosmetics Co., Inc.	New York	3545 Webster Avenue, Bronx, New York
Puritan Cosmetics Co.	Missouri	3719 North 14th Street, St. Louis, Missouri
Revlon, Inc.	Delaware	666 Fifth Avenue, New York, New York
Roux Laboratories, Inc.	New York	1841 Park Avenue, New York, New York
Shulton, Inc.	New Jersey	Route 46, Clifton, New Jersey
Yardley of London, Inc.	New Jersey	Union Boulevard, Totowa, New Jersey

(c) Various of the plaintiff companies which are incorporated or have their principal place of business in a state other than New York, are licensed to do business or are doing business in this judicial district.

3. Defendant Anthony J. Celebrezze is the Secretary of Health, Education and Welfare (herein called the "Secretary") and is the officer of the Department of Health, Education and Welfare (herein called the "Department") who is charged with the administration of the Act. The Secretary is authorized by Section 701(a) of the Act to promulgate regulations for the efficient enforcement of the Act, and by Section 706(b) and (c) of the Act to provide by regulation for separately listing color additives for use in food, drugs and cosmetics, for the certification of batches of color additives so listed and for the exemption of certain color additives from the requirement of certification. Defendant George P. Larrick is the Commissioner of Food and Drugs (herein called the "Commissioner") and is responsible for the supervision and direction of the Food and Drug Administration (herein called the "FDA"), an operating agency of the Department. 22 Fed. Reg. 1045, 1051. The Secretary has purported to assign to the Commissioner the functions vested in the Secretary and in the Department under the Act. 25 Fed. Reg. 8625. The Commissioner is the officer who promulgated the Color Regulations. Each defendant is an officer of an agency of the United States purporting to act in his official capacity or under color of legal authority.

[fol. D] 4. (a) The matter in controversy exceeds the sum or value of $10,000, exclusive of interest and costs, and the action arises under the laws of the United States, namely, the Act, and more particularly, the amendment designated as the "Color Additive Amendments of 1960," enacted July 12, 1960, 74 Stat. 397 (herein called the "Color Additive Amendments"), and also the Administrative Procedure Act, 60 Stat. 237, as amended, 5 USC §1001, *et seq.*

(b) This Court has jurisdiction of this action by virtue of 28 USC §§1331(a) and 1337.

(c) This action is authorized by 28 USC §§2201 and 2202, and 5 USC §1009. The plaintiffs are persons suffering legal wrong because of the action of the Commissioner in promulgating the Color Regulations and are adversely affected and aggrieved by such action. This is a case of actual controversy which requires a declaration of the rights and other legal relations of the plaintiffs, as the interested parties seeking such declaration, and, more particularly, a declaration with respect to the invalidity of certain provisions of the Color Regulations, in the respects alleged in this complaint.

(d) Venue in this judicial district is proper by virtue of 28 USC §1391(e)(4).

Cosmetics Affected by this Count.

5. Various of the plaintiff companies manufacture, distribute and sell lipstick, rouge, eye makeup colors, nail polish and enamel, face powder, leg applications, suntan lotions and oils, hair dye products and other cosmetics intended for applying color to the human body, all of which products are in this count at times collectively called the "finished cosmetic products."

6. Cosmetics intended for applying color to the human body contain a dye or pigment. Dyes and pigments are also used to impart color to food, drug and cosmetic products. Dyes and pigments used for such purpose are known in the color, food, drug and cosmetic industries as, and are herein called, "color additives." The term "color additive" signifies that the dye or pigment is an ingredient of the food, drug or cosmetic product, as the case may be, and has been added for the sole purpose of imparting the desired color.

7. There are two categories of color additives, namely, (a) colors derived from natural sources, animal, vegetable or mineral, known in said industries as, and herein called, "natural colors," and (b) colors made by a process of synthesis, known in said industries as, and herein called, "synthetic dyes and pigments." Synthetic dyes and pigments are generally superior to natural colors from the standpoint of uniformity, tinctorial value and application properties and therefore became widely used as the color additive in foods, drugs and cosmetics. The synthetic dyes and pigments most widely used as such color additives are chemical compounds which are or can be derived from coal tar or coal-tar constituents, known in said industries as, and herein called, "coal-tar colors." Coal-tar colors are the color additives generally used to add color to the finished cosmetic products.

8. Color additives are manufactured by chemical and dye corporations (herein called the "color manufacturers"), who have wide experience and specialized skills in the chemical processes required to produce proper dyes and pig-
[fol. E] ments. The color manufacturers sell the color additives to the food, drug and cosmetic manufacturers, including the plaintiff companies.

The Listing and Certification of Color Additives Under Prior Law.

9. The Secretary of Agriculture, who was charged with administration of the Food and Drug Act enacted in 1906 (34 Stat. 768) (herein called "the 1906 Act"), which was not applicable to cosmetics, promulgated a list of coal-tar colors, with specifications therefor, which were harmless and could be safely used in foods and confectionery. A voluntary practice was established of having color manufacturers submit to the Department of Agriculture samples from each batch of listed coal-tar colors to be analyzed for purity and compliance with the specifications for the listed coal-tar color, and to be certified as harmless, and a

batch so certified received an official certification number which accompanied the color through all subsequent packagings.

10. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040) (herein called "the 1938 Act"), which extended statutory regulation to cosmetics, prohibited the adulteration or misbranding of any food, drug, device or cosmetic in interstate commerce, accorded statutory basis to such prior practice of listing coal-tar colors and having batches certified, and specifically applied such requirement to drugs and cosmetics, as well as to food products.

11. The 1938 Act provided, in Section 601 (a) and (e), that a cosmetic is deemed adulterated if "it bears or contains any poisonous or deleterious substance which may render it injurious to users" under certain conditions of use, or "it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604."

12. Section 604 of the 1938 Act provided as follows:

> "CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS
>
> "Sec. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents."

13. The Secretary of Agriculture promulgated regulations which, among other things, prescribed the procedures to be followed for admitting coal-tar colors to listing and for obtaining subsequent certification of batches of such listed colors. Such regulations defined coal-tar colors as follows (21 CFR 135.1, 1949 ed.):

> "(a) The term 'coal-tar color' means articles which (1) are composed of or contain any substance derived

from coal tar, or any substance so related in its chemical structure to a constituent of coal tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, cosmetic, or the human body or any part thereof, are capable (alone or through reaction with other substance) of imparting color thereto."

14. There was thus established by the 1938 Act and the regulations thereunder, what was essentially a licensing system for coal-tar colors, as the color additives to be used in foods, drugs and cosmetics, involving pretesting and list-[fol. F] ing of the color additive and certification of color batches (hereinafter called the "color licensing system").

15. Pursuant to the color licensing system and prior to enactment in 1960 of the Color Additive Amendments, there were listed, with specifications, 118 coal-tar colors which had been established as harmless and suitable for use in foods, drugs and cosmetics. The coal-tar colors so listed included substantially all the color additives which were added to and used in lipsticks, rouges and nail polish and enamels, and in excess of 95% of such cosmetics sold in the United States contained as their color additive a listed and certified coal-tar color.

Emergency Which Resulted in Enactment in 1960 of the Color Additive Amendments.

16. On December 15, 1958 the Supreme Court, in *Flemming* v. *Florida Citrus Exchange*, 358 U. S. 153, sustained a position taken by the Secretary and the Commissioner, and held (a) that a coal-tar color to be listed and certified had to be entirely lacking in toxicity and be wholly innocuous and without any adverse physiological effect, (b) that the word "harmless" as used in the provision of the 1938 Act "for the listing of coal-tar colors which are harmless" had to be applied in an absolute sense, i.e., harmless per se, (c) that if a coal-tar color in any quantity, regard-

less of how substantial or concentrated, could produce any toxicity, it could not be listed as harmless and suitable for use in foods, drugs or cosmetics, even if established to be harmless with respect to a particular use in an article of food, drug or cosmetic, or with respect to the tolerances or quantities involved in such use, and (d) that the Secretary had no power to establish tolerances for the use of coal-tar colors in the finished product, though harmless in its particular use and application.

17. As a result of such position, the Secretary and the Commissioner reviewed all listed coal-tar colors and felt compelled to delist those which, on the basis of the absolute standard, could in any quantity or concentration produce some toxicity, even though such colors were in fact harmless in the quantity used in a particular article of food, drug or cosmetic.

18. The delisting of coal-tar colors which ensued and was anticipated, removed and threatened to continue to remove from the market products which had been widely sold and distributed and which had received extensive consumer acceptance, and which experience had established were harmless and safe in use, and such delisting threatened to destroy large segments of industry.

19. The Secretary prepared and sponsored a proposed bill for enactment by Congress, as a relief measure, which would empower him to allow color additives to be used in finished products with tolerance limitations, and to apply as the test for listing, the so-called "safe-for-use" principle, and thereby remedy the inflexibility of the 1938 Act, as interpreted to require application of the so-called "harmless per se" principle.

20. In transmitting the proposed legislation to the Speaker of the House, the Secretary explained the emergency requiring such remedial legislation. Such emergency was stated, in the same language as used by the Secretary, in the House Report on the proposed legislation, enacted

[fol. G] as the Color Additive Amendments (H. R. No. 1761, p. 9, dated June 7, 1960, 86th Cong. 2d Sess.), as follows:

"NEED FOR LEGISLATION

* * * * * *

"Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

"The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

"There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by the Department of Health, Education, and Welfare."

21. The color licensing system voluntarily followed under the 1906 Act and prescribed by the 1938 Act was limited to coal-tar colors. Natural colors and synthetic dyes and pigments which were not coal-tar colors had not been subjected to the color licensing system.

22. The Secretary, in seeking remedial legislation to forestall the emergency above described, also proposed that the scope of the color licensing system be broadened to cover not only coal-tar colors, but all other colors.

23. The House Report (H. R. No. 1761, pp. 10-11) explained the second change to be accomplished by the proposed legislation, as follows:

> "The bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term 'coal-tar color.' The bill would therefore establish common ground rules for all such colors.
>
> "Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. • • • "

24. The proposed legislation was based upon the definition of coal-tar colors, quoted in paragraph 13 hereof, which [fol. H] had been contained in the regulations for over twenty years, but substituted the term "color additive" for the term "coal-tar color" so as to cover both general categories of color additives, as described in paragraph 7 hereof, namely, the natural colors and the synthetic dyes and pigments. Thus, the definition of "color additive" contained

in the bill, and retained without change in the Color Additive Amendments (Section 201 of the Act), is as follows:

"(t)(1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B), when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays."

25. Throughout the hearings on the bill, as well as in the House Report, it was emphasized by the Secretary, the Commissioner and other Government officials that the bill had a two-fold purpose, namely, (a) to relieve the emergency created by the delisting of colors, with the danger of driving out of business the color manufacturers and the food, drug and cosmetic manufacturers who used color additives as an ingredient of their finished product, and (b) to extend the color licensing system from coal-tar colors to natural colors and to synthetic dyes and pigments not coal-tar colors.

26. The Color Additive Amendments were proposed and enacted against the background hereinabove described.

The Color Additive Amendments of 1960.

27. The Color Additive Amendments, effectuating the two-fold purpose hereinabove described, authorized the Secretary to prescribe "a tolerance limitation . . . to assure that a proposed use of a color additive will be safe" (Sec. 706(b)(1)), and otherwise gave effect to the "safe-for-use" principle, and also defined color additives, as quoted in paragraph 24 hereof, to include natural and non-coal-tar colors (Sec. 201(t)).

28. Under the heading "Listing of Colors," such Amendments authorized the Secretary by regulation to "provide for separately listing * * * color additives for use in or on cosmetics" (Sec. 706(b)(1)), and under the heading "Certification of Colors," such Amendments further authorized the Secretary by regulation to provide for certification "of batches of color additives listed pursuant to subsection (b)" (Sec. 706(c)).

29. Unless the color additive received a new and separate listing and batches of the color additive were thereafter certified or exempted from certification, the use of such color additive in a food, drug or cosmetic product caused such product automatically to be deemed "unsafe" and "adulterated" (Sec. 706(a), 601(e)).

[fol. I] 30. Prior to such new listing, and in order to establish safety with respect to a particular use, the Color Additive Amendments require that each color additive be subject to scientific investigations, involving extensive and costly pharmacological and toxicological tests estimated to require two and one-half years for completion. To prevent removal from the market of all food, drug and cosmetic products which contain color additives, such Amendments, under the heading "Provisional Listings of Commercially Established Colors," authorized provisional listing of "color additives * * * pending the completion of the scientific investigations needed as a basis for making determina-

tions as to listing of such additives" (74 Stat. 397, 404, Title II, Sec. 203(a)(1); 21 U. S. C. fn. after §376(f)).

31. The Color Additive Amendments further provided that certain color additives would be "deemed" to be provisionally listed (a) if the color additive had been listed and certified on the day preceding the enactment date of such Amendments, namely, July 12, 1960 (having reference to coal-tar colors as the only colors required to be listed and certified prior to such Amendments), and (b) if the color additive had been commercially used or sold prior to such enactment date for any use or uses in food, drugs or cosmetics (having reference to the colors not previously required to be listed and certified) (74 Stat. 397, 405, Title II, Sec. 203(b); 21 U. S. C. fn. after §376(f)).

32. The Color Additive Amendments provided a general period of two and one-half years from their enactment date for the provisional listing of color additives of the categories set forth in paragraph 31. Because "the scientific investigations needed as a basis for making determinations as to listing" of color additives might require more than two and one-half years, the Secretary was authorized, with respect to a particular provisional listing of a color additive, to extend such two and one-half year period on a showing that such scientific investigations were being carried to completion in good faith (74 Stat. 397, 404, Title II, Sec. 203(a)(1)(2); 21 U. S. C. fn. after §376(f)).

33. Pursuant to said statutory provisions for provisional listings, the Commissioner issued provisional regulations which set forth the names of color additives which were provisionally listed for use in foods, drugs and cosmetics. Such provisional listings included coal-tar additives which had been previously listed and certified, and also certain natural and non-coal-tar synthetic colors as to which listing and certification had not been previously required (21 CFR 8.501).

34. All the color additives provisionally listed by the Commissioner were colors, that is, dyes or pigments, and did not include finished cosmetic products or non-color ingredients of such products.

35. Promptly after enactment of the Color Additive Amendments and after consultation with authorized representatives of the FDA, the Association and various of the plaintiff companies undertook, in conjunction with the color manufacturers, to perform, or to arrange for the performance of, the scientific investigations and pharmacological and toxicological tests as to dyes and pigments to be used as color additives in cosmetics, as a basis whereby the Commissioner could make determinations as to listing such color additives. The plaintiff companies have not generally commenced or made or arranged for any such scientific investigations or pharmacological or toxicological tests as a basis for obtaining the listing of a finished cosmetic product, or [fol. J] the ingredients therein, other than the dye or pigment. Until the promulgation of the Color Regulations on June 22, 1963, no recommendation or suggestion had been made by representatives of the FDA, or in public notices issued by it, that listings of finished cosmetic products or of such ingredients therein would be required under the Color Additive Amendments.

36. With respect to certain dyes or pigments, required scientific investigations could not be completed within the two and one-half year period prescribed by the Color Additive Amendments, which expired January 12, 1963, and the Commissioner extended the provisional listing of such dyes or pigments. At the present time, only dyes or pigments which have actually been provisionally listed by regulation for use in cosmetics are permitted in cosmetics, the so-called "deemed" provisional listings, referred to in paragraph 31, having expired on January 12, 1963.

37. The Act, as amended by the Color Additive Amendments, in effect, places foods, drugs and cosmetics, and

specific ingredients thereof, with respect to the safety of their composition, in three general categories, namely:

(a) Foods, old drugs and cosmetic products,—which can be manufactured and sold without advance approval or clearance by FDA, which, however, has the power, authority and responsibility of proceeding under the Act if the product contains a poisonous or deleterious substance which might render it injurious to users;

(b) New drugs and antibiotic drugs,—which cannot be sold without advance approval or clearance by FDA of the finished product, herein called "premarketing clearance;" and

(c) Specific ingredients of the product,—which, in the case of foods, are "food additives," and, in the case of foods, drugs and cosmetics, are the dyes or pigments known as "color additives," which specific color ingredients are subject to "premarketing clearance" by way of listing in appropriate regulations and by certification or exemption from certification under the color licensing system.

38. Premarketing clearance is not required by the Act for finished cosmetic products, but the safety of such products is governed by Section 601(a) with reference to a cosmetic which contains a poisonous or deleterious substance which might render it injurious to users.

The Color Regulations, and Their Unauthorized and Expanded Definition of Color Additives to Include Finished Cosmetic Products.

39. The Commissioner promulgated the Color Regulations, which, among other things, prescribed the color licensing system for color additives for use in food, drugs and cosmetics, and imposed with respect thereto additional requirements to give effect to the "safe-for-use" principle

embodied in the Color Additive Amendments. The Color Regulations were effective on the date of publication in the Federal Register, which was June 22, 1963, except that they grant a transitional period of two years for certain "coal-tar" hair dyes, and also provide that Section 8.30 of the Color Regulations, which relates to color additive mixtures, shall become effective one year after such publication.

[fol. K] 40. The Color Regulations initially gave the term "color additive" the same definition contained in the Act, as quoted in paragraph 24 hereof, but elsewhere the Color Regulations expanded the definition of the term by the following additional provision (Section 8.1(f)):

> "Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives'."

41. The term "color additive", as defined by Congress in the Color Additive Amendments, and as used in the color industry and in the food, drug and cosmetic industries for over fifty years, means the ingredient in the food, drug or cosmetic which imparts color thereto, namely, the dye or pigment, whether synthetic or natural, and does not mean the finished product which contains the dye or pigment as one of many ingredients. All the color additives, as such term is defined by the Color Additive Amendments, used by each of the plaintiff companies in the finished cosmetic products, are listed in currently outstanding provisional regulations promulgated by the Commissioner. Finished cosmetic products are not listed in any currently outstanding regulation within the meaning of Section 706(a) of the Act, and the manufacture, sale and distribution by the plaintiff companies of finished cosmetic products constitute, according to the effect of the definition of "color additive" contained in the Color Regulations, an adulteration within the meaning of Section 601(e) of the Act.

42. By this expedient of expanding the meaning of the term "color additive" and by defining it to include the fin-

ished cosmetic product which contains the color additive, the Commissioner arrogated to himself a power and authority not granted to him, or to the Secretary, in the Color Additive Amendments, or otherwise, and not assigned to him by the Secretary, to establish a color licensing system, not only for the dyes and pigments, as authorized by Congress, but also for the finished cosmetic products, namely, lipsticks, rouge, eye makeup colors, hair dye products and related cosmetics intended for applying color to the human body, and thereby impose a requirement of premarketing clearance for the finished cosmetic products.

43. The Commissioner evidenced his intent to exceed the authority and power granted the Secretary by the Color Additive Amendments, and by regulation to assume the authority and power to require premarketing clearance of the finished cosmetic products, in his press release announcing the Color Regulations, wherein he stated, in substance and effect, that whereas "Previously only color of the coal tar type ingredients had been subject to the requirement for pre-marketing proof of safety," "Under the new regulations, FDA will require that an entire product—not just the color ingredient—be shown by the manufacturer to be safe before it is released for sale."

44. The Color Regulations, by defining the term "color additive" to include the finished cosmetic product and not merely the color ingredient, are not in accordance with law; are in excess of the statutory jurisdiction, authority and limitations of the defendants; are short of statutory right, are in derogation of the basic statutory purpose; are contrary to the statutory provisions on which they purport to be based; constitute an unwarranted and unlawful attempt by the Commissioner to establish premarketing clearance of the finished cosmetic products before such products may be sold and thereby seek to extend the scope of the Act [fol. L] and the color licensing system prescribed thereby to a major segment of the cosmetic industry to which Congress determined premarketing clearance should not apply,

and seek to obtain by regulation power and authority which Congress has refrained from granting by statute; expand the scope and application of a criminal and forfeiture statute and subject to criminal and forfeiture penalties matters which Congress did not provide should be subject thereto; and are illegal, void and of no effect.

Hardship Imposed on Plaintiffs by Such Definition of Color Additives to Include Finished Cosmetic Products.

45. Compliance with the unauthorized and illegal Color Regulations by the plaintiff companies is an extremely burdensome and costly task. The Color Regulations, by their expanded and unauthorized definition of a "color additive" to include the finished cosmetic product, among other things, require the plaintiff companies to petition the Commissioner for the listing of each finished cosmetic product made or sold by the plaintiff companies and to obtain certification or exemption from certification of batches of the finished cosmetic product. The petition for such listing requires that there be set forth the chemical identity and composition of the finished cosmetic product, its physical, chemical and biological properties, and specifications describing its components. Since the plaintiff companies purchase many of the ingredients of the finished cosmetic products from other manufacturers, such information is not within their knowledge or available to them. Such petition for listing also requires the performance of costly chemical and physical tests, and a description of the methods used in, and the facilities and controls used for, the production of the finished cosmetic product to be listed.

46. Compliance with the Color Regulations would require the plaintiff companies to change established business practices, seriously curtail the launching and market testing of proposed new finished cosmetic products, and cause major and costly disruption of their businesses. Such compliance with the Color Regulations will also require plaintiff companies in effect to disclose and make available to others

secret ingredients developed by them, which constitute a vital factor in the success of their businesses and a valuable property right, will permit appropriation by others of such secret ingredients and will discourage research and developmental work for the improvement and development of cosmetic products.

47. Each petition for listing must be accompanied by a $2,600 fee, and a separate listing appears to be required for each product and for each shade of each product. Also, unless exempted from certification substantial certification fees must be paid with respect to each batch of the finished cosmetic product required to be certified. (28 Fed. Reg. 6439, 6448, §8.50). Included among the plaintiffs are companies known as private brand manufacturers which make finished cosmetic products for other cosmetic companies to be sold by them under their respective trademarks, trade names or other labels. Such private brand manufacturers make hundreds of separate formulae covered by the unauthorized expanded definition of the term "color additive", and the cost to them of compliance with the color licensing system, as unlawfully applied to their products, would amount to many millions of dollars and would destroy their businesses. The fees prescribed by the Color Regulations [fol. M] for listing and certification, when applied to the requirements applicable to each finished cosmetic product by reason of the unauthorized expanded definition of the term "color additive", are confiscatory and constitute an unlawful and unauthorized taking of property, and an illegal and discriminatory tax on a single industry, imposed by an administrative agency without statutory authority.

48. The Association acts in behalf of the plaintiff companies and its other members in seeking to clarify the scientific investigations and pharmacological and toxicological tests which FDA may regard as sufficient to accomplish required listing and certification or exemption from certification, in making contracts with consulting laboratories for such investigations and tests, and otherwise acts for the

plaintiff companies and its other members in respect of the application of the Color Regulations to their products and the efforts of its members to understand the Color Regulations and to comply therewith. The Association is recognized by the FDA as the representative of all the plaintiff companies and other cosmetic manufacturers with respect to various aspects of their compliance with the color licensing system. By reason of its activities and functions with respect to the color licensing system and the Color Regulations, the Association is affected by such Regulations.

49. The Act prescribes criminal penalties, including imprisonment and fine, and also authorizes multiple seizures and condemnation of foods, drugs and cosmetics and injunction proceedings for noncompliance with provisions of the Act and regulations thereunder.

50. The Color Regulations are formal and final regulations, are self-executing and written in mandatory terms and impose obligations upon the plaintiff companies. The adoption and promulgation of the Color Regulations impose a duty upon the defendants to require plaintiff companies to comply with them, in accordance with their terms. The defendants have determined to require compliance with the Color Regulations, in accordance with their terms, and have so advised the plaintiffs and all other persons manufacturing and selling cosmetics, and there is an actual and immediate threat that such compliance will be required of the plaintiff companies, and that the Color Regulations will be enforced, in accordance with their terms. The effect of the Color Regulations, unless this Court enters a judgment declaring that certain of their provisions referred to in this complaint are unwarranted, unauthorized and unlawful, is to require the plaintiff companies, in order to avoid criminal prosecution, proceedings for the seizure, condemnation and forfeiture of their products affected thereby and injunctive proceedings, to comply with the Color Regulations, with the tremendous expense and other burdens entailed in such compliance, as hereinabove alleged, or to fail to

comply with the Color Regulations, in so far as they exceed the statutory authority of the defendants and are illegal, and thereby incur the risk of the institution of one or more of such proceedings. The business of the plaintiff companies is a highly competitive one, and many millions of dollars are expended each year in advertising their products and in establishing and maintaining consumer confidence in and acceptance of their products, and consumer confidence in the reputation and integrity of the plaintiff companies. The mere institution of any of the foregoing proceedings against any of the plaintiff companies, or any of their products, regardless of the merits or eventual outcome of such proceedings, will have a serious, substantial and adverse effect on the business of the company involved, since the consumer would regard institution of any such [fol. N] proceeding as indicating lack of safety of the cosmetic involved, and the reputation and integrity of the manufacturer of such cosmetic, and the good will associated with its name, would be forthwith adversely affected, with serious and costly consequences to its business. The consequences of a successful criminal or seizure proceeding are additionally severe and could result in a fine, imprisonment, or both, and condemnation and forfeiture of cosmetics having substantial value. The adoption and promulgation of the Color Regulations and the application thereof to the plaintiff companies, and to their businesses, is an immediate and real one, and has an immediate and substantial effect upon the conduct of the plaintiffs, will cause them great and irreparable damage and injury and will substantially and adversely affect their business, and each of the plaintiffs has a substantial, immediate and real interest in the issue of the validity or invalidity of the Color Regulations, in the respects alleged in this complaint, and there exists between the parties an actual controversy, justiciable in character, as to such validity or invalidity of the Color Regulations.

51. More particularly, there exists between the parties an actual controversy, justiciable in character, as to whether

the plaintiff companies may lawfully, without subjecting themselves to criminal prosecution, seizure, condemnation and forfeiture of their products and injunctive actions, continue to manufacture and sell the finished cosmetic products without obtaining therefor premarketing clearance by the Commissioner, and without complying with the requirements of the color licensing system with respect to the entire product, even though the color additive or color ingredient has been pretested, listed and certified or otherwise is in full compliance with the color licensing system. The defendants, through the Color Regulations, in press releases and elsewhere, have taken the position that even though the color ingredient or color additive in the finished cosmetic product has been pretested, listed and certified or has been exempted from certification, the finished cosmetic product may not be sold unless it has received premarketing clearance, and has also complied with the pretesting, listing and certification, or exemption from certification, requirements of the color licensing system. The controversy between the parties under this count of the complaint turns upon the legal validity of the Color Regulations in such respect, which Regulations operate to impose the burden, hardship and irreparable damage and injury upon the plaintiff companies hereinabove alleged.

52. If the statutory definition of a color additive can be expanded by the Commissioner to include the finished cosmetic product, then, in as much as none of such products has been listed in any regulation and the two and one-half year period for "deemed" provisional listings, as described in paragraph 31, expired on January 12, 1963, all such products manufactured and sold by the plaintiff companies or by other cosmetic manufacturers at least since June 22, 1963, the date the Color Regulations were promulgated, would automatically be deemed unsafe and adulterated, with the consequence that such products, and the plaintiff companies, may now face the penalties imposed by the Act for the sale of adulterated cosmetic products. Also, on the

basis of such expansion by the Commissioner of the statutory definition of a color additive to include the finished cosmetic product, no new lipstick, rouge, eye makeup color, hair dye product or other new cosmetic intended for coloring the human body could be manufactured and sold without the premarketing clearance prescribed by the Commissioner, and all such new cosmetic products would also automatically be deemed unsafe and adulterated. The plaintiff companies require a declaration of whether their action in [fol. O] manufacturing and selling, and in continuing to manufacture and sell, the finished cosmetic products without having obtained premarketing clearance is now in violation of the Act, and automatically causes all such products to be deemed unsafe and adulterated.

53. Plaintiffs have no prompt, adequate and effective remedy at law, and this action is the only means available to them for the protection of their rights, and for protection against the immediate, real, substantial and irreparable damage and injury which the plaintiff companies face, as hereinabove alleged.

Second Count

54. The statements in paragraphs 1 to 39, inclusive, 45 to 50, inclusive, and 53, are adopted by reference.

Unauthorized and Illegal Application of the Color Licensing System to Diluents and the Classification of All Non-Color Ingredients as Diluents.

55. Dyes and pigments, as pure colors, have a strength in excess of that required to impart color to foods, drugs or cosmetics, and must, if utilized for such purpose, be diluted by an inert substance. Such inert substance used to dilute the color and diminish the strength of a dye or pigment is known in the color, food, drug and cosmetic industries as, and is herein called, "the diluent." The color manufacturer may sell the dye or pigment to the plaintiff companies as

a pure color or in a diluent which dilutes and diminishes its strength.

56. A dye or pigment, as a color additive, is also used to impart color to finished cosmetic products which do not have the purpose of applying color to the human body, such as perfumes, toilet water and colognes, bath salts, deodorants, and the like. All cosmetics which contain a dye or pigment added for the purpose of applying color to the human body or of imparting color to the cosmetic are in this count at times called the "finished cosmetic products."

57. The finished cosmetic products contain (a) a dye or pigment, (b) a diluent as defined in paragraph 55 and (c) a number of other ingredients (herein called the "other ingredients") intended for a variety of other purposes. The other ingredients are neither color additives nor diluents, and are not regarded as such in the color, food, drug or cosmetic industries. The other ingredients are purchased by the plaintiff companies from a variety of other manufacturers.

58. The Color Regulations initially gave the term "color additive" the same definition contained in the Act, as quoted in paragraph 24 hereof, namely, as meaning colors derived from natural sources and all synthetic dyes and pigments, instead of being limited to coal-tar colors, but then expanded the definition of the term by the following additional provision: "This includes all diluents" (§8.1(f)).

59. The Color Regulations define a "diluent" as follows (§8.1(m)):

> "(m) The term 'diluent' means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. [fol. P] The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for ex-

ample sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body."

60. The term "color additive", as defined by Congress in the Color Additive Amendments, and as used in the color industry and in the food, drug and cosmetic industries for over fifty years, means the ingredient in the food, drug or cosmetic which imparts color thereto, namely, the dye or pigment, whether synthetic or natural, and does not mean the diluent or the other ingredients. All the color additives, as such term is defined by the Color Additive Amendments, used by each of the plaintiff companies in the finished cosmetic products are listed in currently outstanding provisional regulations promulgated by the Commissioner. The Color Additive Amendments provide for the listing of "color additives for use in or on cosmetics" (Section 706(b)(1)), and make it clear that the requirement for listing does not apply to diluents, by providing only "for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b)" (Section 706 (c)). The other ingredients are not listed in any currently outstanding regulation within the meaning of Section 706(a) of the Act, and the manufacture, sale and distribution by the plaintiff companies of finished cosmetic products containing the other ingredients constitute, according to the effect of the definition of "color additive" contained in the Color Regulations, an adulteration within the meaning of Section 601(e) of the Act.

61. By this expedient of expanding the meaning of the term "color additive" and by defining it to include diluents, and by defining diluents to mean all or substantially all the other ingredients, the Commissioner arrogated to himself a power and authority not granted to him, or to the Secretary, in the Color Additive Amendments, or otherwise, and not assigned to him by the Secretary, to establish a color licensing system, not only for the dyes and pigments, as

authorized by Congress, but also for all the other ingredients, and thereby apply to the other ingredients a requirement of advance approval or clearance which the Act limits to the color ingredient only.

62. The Color Regulations, by defining the term "color additive" to include diluents and not merely the color ingredient, and by defining diluents to mean all or substantially all the other ingredients, are not in accordance with law; are in excess of the statutory jurisdiction, authority and limitations of the defendants; are short of statutory right; are in derogation of the basic statutory purpose; are contrary to the statutory provisions on which they purport to be based; constitute an unwarranted and unlawful attempt by the Commissioner to establish premarketing clearance of all or substantially all the other ingredients before the finished cosmetic product may be sold, and thereby seek to extend the scope of the Act and the color licensing system prescribed thereby to the various industries which manufacture and sell the other ingredients, and seek to obtain by regulation power and authority which Congress has refrained from granting by statute; expand the scope and application of a criminal and forfeiture statute and subject to criminal and forfeiture penalties matters which Congress did not provide should be subject thereto; and are illegal, void and of no effect.

[fol. Q]

Hardship Imposed on Plaintiffs by Such Application of the Color Licensing System to Non-color Ingredients

63. The hardship, burden and expense of compliance with the unauthorized and illegal Color Regulations, and the unauthorized and illegal application of the color licensing system to all or substantially all the other ingredients of the finished cosmetic products, and the consequences thereof, are substantially as alleged in paragraphs 45 to 47, inclusive, and 50.

64. Compliance with the unauthorized and illegal Color Regulations, as they purport to be applicable to all or substantially all the other ingredients of the finished cosmetic products, in such an extremely burdensome and costly task and is so onerous that manufacturers or vendors of the other ingredients are unwilling to undertake the burden and expense involved, so that the plaintiff companies must either assume such burden and expense or be unable to use the other ingredients necessary to the finished cosmetic products.

65. There exists between the parties an actual controversy, justiciable in character, as to whether the plaintiff companies may lawfully, without subjecting themselves to criminal prosecution, seizure, condemnation and forfeiture of their products and injunctive actions, continue to manufacture and sell the finished cosmetic products without obtaining premarketing clearance by the Commissioner for the other ingredients, and without complying with the requirements of the color licensing system with respect to the other ingredients, even though the color additive or color ingredient has been pretested, listed and certified or otherwise is in full compliance with the color licensing system. The defendants, through the Color Regulations, and elsewhere, have taken the position that even though the color ingredient or color additive in the finished cosmetic product has been pretested, listed and certified or has been exempted from certification, the finished cosmetic product may not be sold unless the other ingredients therein have also complied with the pretesting, listing and certification, or exemption from certification, requirements of the color licensing system and have received premarketing clearance. The controversy between the parties under this count of the complaint turns upon the legal validity of the Color Regulations in such respect, which Regulations operate to impose the burden, hardship and irreparable damage and injury upon the plaintiff companies hereinabove alleged.

66. If the statutory definition of a color additive can be expanded by the Commissioner to include diluents, which he defines as meaning all or substantially all the other ingredients, then, in as much as none of such other ingredients has been listed in any regulation and the two and one-half year period for "deemed" provisional listings, as described in paragraph 31, expired on January 12, 1963, all the finished cosmetic products manufactured and sold by the plaintiff companies or by other cosmetic manufacturers, at least since June 22, 1963, the date the Color Regulations were promulgated, which contain such other ingredients, would automatically be deemed unsafe and adulterated, with the consequence that such products, and the plaintiff companies, now face the penalties imposed by the Act for the sale of adulterated cosmetic products. Also, on the basis of such expansion by the Commissioner of the statutory definition of a color additive to include diluents, so defined as meaning all or substantially all the other ingredients, no new cosmetic product which contains such other ingre- [fol. R] dients could be manufactured and sold without the premarketing clearance prescribed by the Commissioner, and all such new cosmetic products would also automatically be deemed unsafe and adulterated. The plaintiff companies require a declaration of whether their action in manufacturing and selling, and in continuing to manufacture and sell, the finished cosmetic products without having complied with the color licensing system, as applied by the Commissioner to the other ingredients, or without having obtained premarketing clearance for the other ingredients, is now in violation of the Act, and automatically causes all such products to be deemed unsafe and adulterated.

THIRD COUNT

67. The statements in paragraphs 1 to 39, inclusive, 45 to 50, inclusive, 53, 55, 58, 59 and 64, are adopted by reference.

Unauthorized and Illegal Application of the Act, the Color Regulations, Premarketing Clearance and the Color Licensing System to Hair Dyes.

68. Various of the plaintiff companies are engaged in the manufacture, distribution and sale in interstate commerce of finished cosmetic products designed for the purpose of coloring the hair, including products known as color shampoos, color rinses and color tints (herein at times called "hair dye products"). Hair dye products contain color additives, as defined in Section 201(t) of the Act. The color additives which are primarily used in hair dye products are coal-tar colors, as described in paragraph 7, and all or substantially all hair dye products manufactured or sold by plaintiff companies contain coal-tar colors. None of such hair dye products consists solely of a coal-tar color or dye, but all such products also contain, in addition to diluents, as defined in paragraph 55, other ingredients, such as wetting agents, hair conditioners, emulsifiers, shampoos and similar ingredients which increase the effectiveness of the product's hair coloring properties or improve the condition of the hair (herein called the "other ingredients").

69. The 1938 Act specifically exempted coal-tar hair dyes, other than eyelash and eyebrow dyes, from the provisions of Section 601(a) and (e) if their label and labeling contained a "caution" and directions for testing for possible skin irritation, known as patch-testing. Such Section provided:

> "SEC. 601. A cosmetic shall be deemed to be adulterated—
>
> "(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided,* That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed

thereon: 'Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness', and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term 'hair dye' shall not include eyelash dyes or eyebrow dyes.

* * * * * *

[fol. 8] "(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604."

70. Thus, when Congress enacted the 1938 Act to include cosmetics, it determined that the public interest was best served by exempting coal-tar hair dyes from Section 601(a) and from the color licensing system, and by requiring such cautionary statement and adequate directions for preliminary testing.

71. The Commissioner issued regulations under the 1938 Act, which were in effect at the time of the enactment of the Color Additive Amendments, and which defined the term "coal-tar hair dye" used in Section 601(a) of the 1938 Act as including "all articles containing any coal-tar color or intermediate which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual" (21 CFR 1.200). Such regulations were in compliance with and effectuated the statutory exemption for properly labeled hair dye products.

72. Since 1938, the FDA has consistently recognized that such statutory hair dye exemption applies to all hair dye

products containing a coal-tar color or intermediate, and has also consistently recognized that color shampoos, color rinses and color tints are terms used in the cosmetic industry to designate hair dye products which, though serving a dual purpose, are coal-tar hair dyes, and that such dual purpose products, being articles which when applied to the hair alter its color, were within such statutory hair dye exemption if they contained the prescribed cautionary label.

73. FDA officials subsequently regarded such specific statutory exemption for hair dye products as a "loophole" in the law, and the FDA has from time to time sponsored legislation designed to amend the Act to repeal such exemption.

74. The Color Additive Amendments did not change such statutory exemption for hair dyes but on the contrary emphasized the existence and continuance of the hair dye exemption by adding a new Section 602(e) "relating to the circumstances under which cosmetics shall be deemed to be misbranded," which provides that said Section 602(e) shall not apply to "color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of Section 601(a))."

75. The Commissioner, having been unable to obtain repeal of the statutory exemption for hair dyes, has sought by the Color Regulations to change and limit such exemption. Contrary to the language of the Act and its long-standing administration, the Color Regulations (Section 8.1 (f)(u)), in substance and effect and as interpreted by the FDA, narrow and limit the statutory exemption to apply only to the specific coal-tar color ingredients in hair dye products, and then only in so far as such ingredients are specifically covered by the prescribed cautionary label.

76. By such provision of the Color Regulations, which has changed and limited the statutory definition of "hair dye" to certain coal-tar color ingredients in hair dye prod-

ucts, and by the provisions of the Color Regulations quoted in paragraphs 40, 58 and 59 hereof, which changed the statu- [fol. T] tory definitions of a "color additive" to include all finished cosmetic products intended for coloring the human body, and also diluents, and which defined diluents as meaning all or substantially all the ingredients in the finished cosmetic product, the FDA, by the Color Regulations, seeks substantially to change and limit the statutory exemption for hair dyes, as follows:

(a) By applying the exemption of Section 601(a) only to certain coal-tar color ingredients in hair dye products, rather than to the entire product as had previously been the case; and

(b) By subjecting hair dye products, including the above referred to dual purpose products, and the other ingredients of hair dye products, to premarketing clearance and to the color licensing system.

77. To give effect to such attempt to limit the statutory exemption of hair dyes, the Commissioner, by regulation published in the Federal Register on October 3, 1963 (28 Fed. Reg. 10638), deleted the definition of hair dyes contained in Section 1.200 of said regulations referred to in paragraph 71, "the material therein having been superseded by §8.1(u)" of the Color Regulations.

78. By so limiting the hair dye exemption in the Act, the Commissioner arrogated to himself a power and authority not granted to him, or to the Secretary, in the Color Additive Amendment, or otherwise, and not assigned to him by the Secretary, and has thereby imposed a requirement of premarketing clearance and the color licensing system for such products, notwithstanding such specific statutory exemption.

79. The Commissioner evidenced his intent to exceed the authority and power granted the Secretary by the

Color Additive Amendments, and by regulation to assume the authority and power to apply the Color Regulations and the color licensing system to hair dye products exempted by the Act, and also to apply premarketing clearance to such hair dye products, in his press release, dated June 22, 1963, announcing the Color Regulations, wherein he stated, in substance and effect, that the hair dye exemption in the Act offered insufficient protection and that "the purpose of the new regulation is to close this gap," and that "Hair dyes that do not cause a reaction with the patch test must now be demonstrated to be safe before they can be marketed", and again in his press release, dated October 3, 1963, announcing deletion of the definition of hair dyes contained in Section 1.200 of said regulations referred to in paragraph 71, wherein he described the Color Regulations as "limiting the exemption for hair dyes under the Federal Food, Drug, and Cosmetic Act."

80. The Color Regulations, by limiting the statutory exemption of hair dyes and by extending the Act, the Color Regulations and the color licensing system to hair dye products, and in seeking to apply premarketing clearance to hair dye products, are not in accordance with law; are in excess of the statutory jurisdiction, authority and limitations of the defendants; are short of statutory right; are in derogation of the basic statutory purpose; are contrary to the statutory provisions on which they purport to be based; constitute an unwarranted and unlawful attempt by the Commissioner to apply the Act, the Color Regulations and the color licensing system to products which Congress provided should be exempt, and to seek to obtain by regulation power and authority which Congress has refrained from granting by statute; expand the scope and [fol. U] application of a criminal and forfeiture statute and subject to criminal and forfeiture penalties matters which Congress did not provide should be subject thereto; and are illegal, void and of no effect.

Hardship Imposed on Plaintiffs by the Unauthorized and Illegal Regulations Applicable to Exempt Hair Dye Products.

81. Various of the plaintiff companies manufacture and distribute hair dye products which are specifically exempt from the provisions of Sections 601(a) and 601(e) of the Act, but which the Color Regulations now purport to bring within the scope of such provisions, the Color Regulations and the color licensing system, and to which the Color Regulations now purport to apply a requirement of premarketing clearance not authorized by the Act. The hardship, burden and expense of compliance with the unauthorized and illegal Color Regulations, and the unauthorized and illegal application of the Act, the Color Regulations and the color licensing system to hair dye products exempted by the Act, and the consequences thereof, are substantially as alleged in paragraphs 45 to 47, inclusive, and 50.

82. There exists between the parties an ~~actual~~ controversy, justiciable in character, as to whether the plaintiff companies may lawfully, without subjecting themselves to criminal prosecution, seizure, condemnation and forfeiture of their products and injunctive actions, continue to manufacture and sell hair dye products without obtaining premarketing clearance by the Commissioner for the finished product, and for the other ingredients, and without complying with the requirements of the color licensing system with respect to the finished product and the other ingredients, and whether the plaintiff companies must regard the statutory exemption granted to hair dyes under Section 601(a) of the Act as repealed. The defendants, through the Color Regulations and elsewhere, have taken the position that notwithstanding the statutory exemption of hair dyes from Section 601(a) and (e), the defendants can impose substantial limitations on such exemption, and can also impose a requirement for premarketing clearance of hair dye products, and that such products may not be sold,

unless such products, and the other ingredients therein, have received premarketing clearance and have complied with the pretesting, listing and certification requirements of the color licensing system. The controversy between the parties under this count of the complaint turns upon the legal validity of the Color Regulations in such respect, which Regulations operate to impose the burden, hardship and irreparable damage and injury upon the plaintiff companies hereinabove alleged.

[fol. V] FOURTH COUNT

83. The statements in paragraphs 1 to 4, inclusive, and 53, are adopted by reference.

Unauthorized and Illegal Provisions of the Regulations as to Access to Processes and Formulae.

84. Section 704 of the Act, entitled "Factory Inspection", provides that designees of the Secretary may enter any factory, warehouse, or establishment in which food, drugs, devices or cosmetics are manufactured, processed, packed or held, and inspect such factory, warehouse, establishment and "all pertinent equipment, finished and unfinished materials; containers and labeling therein."

85. On October 10, 1962 (76 Stat. 792), the Act was amended to include special and additional inspection provisions, applicable to prescription drugs only, which provide that "the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded" are being manufactured, processed, packed, transported or held. The Act further provides that its special inspection provisions for prescription drugs do not apply to various types of data, such as financial, sales, pricing and research data, which are of a type normally regarded as confidential.

86. Severe penalties are prescribed by the Act for refusal to permit inspection, as authorized by Section 704, including imprisonment and fine, and injunction proceedings.

87. The legislative history of the "Factory Inspection" amendment shows that the authorized inspection power was limited, and that Congress did not intend to authorize inspection or require disclosure of records, processes or formulae of cosmetic manufacturers, or any other persons, except for said special provisions applicable to prescription drugs only.

88. The Color Regulations (§8.28(a)) provide that certification service may be suspended if a person has:

> "(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived."

89. The term "color additive" is defined in the Color Regulations to include lipstick, rouge, eye makeup colors and other finished cosmetic products, and also diluents (§8.1(f)), and diluents are defined in the Color Regulations in effect as including all or substantially all the other ingredients contained in finished cosmetic products which contain a color (§8.1(m)).

90. The Commissioner has, by such provisions of the Color Regulations, in effect expanded the inspection power and authority, as delineated in Section 704 of the Act, so as to authorize inspection, access to and disclosure of all processes and formulae of finished cosmetic products which [fol. W] contain a color, even though the Act specifically limits the inspection of processes to prescription drugs, and nowhere authorizes inspection of, access to or disclosure of formulae, and the Commissioner has thereby arrogated

to himself a power and authority of inspection and access not granted to him, or to the Secretary, in the Act, in the Color Additive Amendments, or otherwise, and not assigned to him by the Secretary.

91. The Commissioner evidenced his intent to exceed the authority and power granted the Secretary by the Act and by the Color Additive Amendments, and by regulation to assume authority and power with respect to factory inspection and the right to obtain access to, and inspection and disclosure of, all "processes, and formulae" contrary to the authority granted by Congress, in his press release announcing the Color Regulations, wherein he stated:

> "The regulations provide that FDA may refuse to certify a color additive—and thus in effect ban it from the market—if the manufacturer refuses FDA inspectors access to manufacturing facilities, processes, and formulas involved in the manufacture of the additive."

92. The Color Regulations, in so far as they purport to empower the Commissioner to obtain access to all processes and formulae involved in the manufacture of color additives, as such term is defined in the Color Regulations, at the penalty to the non-compliant manufacturer of banning his product from the market, are not in accordance with law; are in excess of the statutory jurisdiction, authority and limitations of the defendants; are short of statutory right; are contrary to the statutory provisions on which they purport to be based; constitute an unwarranted and unlawful attempt by the Commissioner to extend his powers and authority with respect to factory inspection and access to matters as to which Congress determined such power and authority should not apply, and seek to obtain, through the device of banning the product from the market, power and authority which Congress has refrained from granting by statute; expand the scope and application of a criminal and forfeiture statute and subject to criminal and forfeiture

penalties matters which Congress did not provide should be subject thereto; and are illegal, void and of no effect.

93. Secrecy of processes and formulae for various cosmetic products is of vital importance to plaintiff companies, as cosmetic manufacturers, and to the successful continuance of their businesses, and plaintiff companies and other cosmetic manufacturers take careful and unusual precautions to preserve such secrecy and not to permit others to obtain knowledge of their processes and formulae.

94. There exists between the parties an actual controversy, justiciable in character, as to whether the defendants may under the Act, or under the Color Additive Amendments, obtain access to all processes and formulae involved in the manufacture of color additives, as defined in the Color Regulations, including finished cosmetic products, under the penalty of having such products banned from the market. The defendants, through the Color Regulations, in press releases and elsewhere, have taken the position that, even though the Act does not grant them access to such processes and formulae, they can in effect obtain such access by refusing certification with the effect of having products of the plaintiff companies banned from the mar- [fol. X] ket. The controversy between the parties under this count of the complaint turns upon the legal validity of the Color Regulations in such respect, which Regulations operate to impose a burden, hardship and irreparable damage and injury upon the plaintiff companies.

Wherefore, plaintiffs pray that this Court:

(1) Issue a judgment declaring that the following provisions of the Color Regulations are not in accordance with law, are in excess of the statutory jurisdiction, authority and limitations of the defendants, and contrary to the statutory provisions on which they purport to be based, and are null and void and of no effect:

(a) The provisions of Section 8.1(f) of the Color Regulations which define as color additives lipstick, rouge, eye makeup colors and related cosmetics intended for coloring the human body, and any other provisions of the Color Regulations which have or may have the effect of defining or treating a finished cosmetic product as a color additive;

(b) The provisions of Section 8.1(f) and (m) of the Color Regulations which define a color additive as including diluents, and which define the term diluent in effect as including all or substantially all the ingredients and components of finished cosmetic products whether or not used to dilute the color and diminish the strength of the dye or pigment;

(c) The provisions of Section 8.1(f) and (u) of the Color Regulations which limit the exemption of hair dyes contained in the Act, and which in effect cause the Act and the Color Regulations to be applied to hair dye products and to the ingredients thereof which are exempt from the provisions of Sections 601(a) and (e) of the Act; and

(d) The provisions of Section 8.28(a)(4) of the Color Regulations, which, by their operation and effect, expand the right of FDA employees with respect to factory inspection, and grant them access to all processes and formulae involved in the manufacture of finished cosmetic products.

(2) Issue a judgment declaring that the finished cosmetic products now being manufactured, distributed and sold by the plaintiff companies, which are intended for applying color to the human body, or which contain a dye or pigment which imparts color to such products, are not to be deemed in violation of Section 601(a) and (e) of the Act because such products have not received premarketing clearance by FDA, or because the ingredients of such products, other than the color ingredient, have not complied with the color licensing system.

(3) Issue a judgment declaring that hair dye products now being manufactured, distributed and sold by the plaintiff companies are not to be deemed in violation of Section 601(a) and (e) of the Act because such products have not received premarketing clearance by FDA, or because the ingredients of such products have not complied with the color licensing system.

(4) Enjoin and restrain the defendants, and all persons acting under their direction and authority, or in active concert or participation with them, from enforcing or causing [fol. Y] to be enforced, or from attempting to enforce or to cause to be enforced, by any administrative action or civil or criminal proceeding or otherwise, the provisions of the Color Regulations alleged herein to be in excess of the statutory authority granted to the Secretary under the Act and to be null and void and of no effect.

(5) Issue a preliminary injunction enjoining and restraining the defendants and said persons from enforcing or causing to be enforced, or from attempting to enforce or to cause to be enforced, by any administrative action or civil or criminal proceeding or otherwise, said provisions of the Color Regulations, and to preserve the status and rights pending conclusion of this action; and

(6) Grant such other or further necessary or proper relief as may be appropriate.

Dated: November 15, 1963.

Breed, Abbott & Morgan, By William L. Hanaway, By Edward J. Ross, Members of the Firm, Attorneys for Plaintiffs, Office and Post Office Address: 1 Chase Manhattan Plaza, New York 5, New York.

[fol. Z] [File endorsement omitted]

[fol. 1]

IN UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket No. 30261

STATEMENT UNDER RULE 15(b)

This is an interlocutory appeal pursuant to Title 28, United States Code, Section 1292(b) from an order of the [fol. 2] United States District Court for the Southern District of New York (Tyler, J.) entered on December 8, 1965 denying appellants' motion to dismiss the complaint and for summary judgment.

This action was commenced by the filing of the complaint on November 15, 1963. On March 3, 1964 defendants moved to dismiss the complaint and on April 10, 1964 plaintiffs cross-moved for summary judgment in their favor. Both motions were denied by Hon. Harold R. Tyler, Jr. in an opinion filed November 17, 1964, which opinion is reported at 235 F. Supp. 648.

Thereafter, on November 20, 1964, the case was assigned to Judge Tyler for all purposes. Defendants' answer was filed on January 5, 1965.

On December 6, 1965 defendants moved again to dismiss and for summary judgment on the grounds that the complaint failed to state a justiciable controversy and that this is an unconsented suit against the United States. Again Judge Tyler denied the motion but this time he certified the questions for immediate appeal. The order was entered on December 8, 1965 and the opinion on which it is based was filed on December 13, 1965.

Appellants applied to this Court on December 16, 1965 for leave to appeal, which application was granted on January 10, 1966. The notice of appeal was filed on January 11, 1966.

[fol. 3]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

63 Civ. 3349

THE TOILET GOODS ASSOCIATION, INC., et al., Plaintiffs,

—v.—

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, Defendants.

NOTICE OF APPEAL—Filed January 11, 1966

Sirs:

Please Take Notice that defendants, Anthony J. Celebrezze, Secretary of Health, Education and Welfare, and George P. Larrick, Commissioner of Food and Drugs, hereby appeal to the United States Court of Appeals for the Second Circuit from the order entered herein by Honorable Harold R. Tyler, United States District Judge, Southern District of New York, on the 8th day of December, [fol. 4] 1965, denying defendants' motion to dismiss the complaint on the grounds that (a) the complaint fails to set forth a justiciable controversy and (b) this is an unconsented suit against the United States, and the defendants appeal from the whole and from each and every part of said order and from the memorandum decision heretofore filed herein on the 13th day of December 1965 on which the said order is based.

This is an appeal pursuant to Title 28, U.S. Code, Section 1292(b) for which leave has been granted by the United States Court of Appeals for the Second Circuit by order dated January 10, 1966.

Dated: New York, N.Y.
January 11, 1966

Yours, etc.

Robert M. Morgenthau, United States Attorney for the Southern District of New York, Attorney for Defendants.

By Arthur S. Olick, Assistant United States Attorney. Office & Post Office Address: United States Court House, Foley Square, New York, N.Y. 10007 Tel.: 264-6319.

To: Messrs. Breed, Abbott & Morgan, 1 Chase Manhattan Plaza, New York 5, N.Y.

[fol. 5]

IN UNITED STATES DISTRICT COURT

ORDER DENYING MOTION TO DISMISS AND FOR SUMMARY JUDGMENT AND CERTIFYING AN IMMEDIATE APPEAL—December 8, 1965

Defendants, having moved for summary judgment dismissing the complaint pursuant to F.R. Civ. Procedure 56 and 28 U.S.C. § 2201, on the grounds that (a) the complaint fails to set forth a justiciable controversy and (b) this is an unconsented suit against the United States, or, alternatively, for an order pursuant to 28 U.S.C. § 1292 (b) certifying said issues for an interlocutory appeal; and

The said motion having come on to be heard before me on December 6, 1965, and Arthur S. Olick, Esq., Assistant United States Attorney, having appeared on behalf of the defendants, and Edward J. Ross, Esq., having appeared on behalf of the plaintiffs,

Now, Therefore, upon the pleadings herein, defendants' notice of motion, dated November 18, 1965, and the affidavits of Arthur S. Olick, sworn to, respectively, on

November 18, 1965, December 1, 1965 and December 6, 1965, in support of the motion for summary judgment, and the affidavits of Edward J. Ross, sworn to, respectively, November 23, 1965 and December 3, 1965, in opposition thereto, and upon all the prior proceedings herein and all the documents heretofore filed herein, and due deliberation having been had, and the Court having rendered its opinion on December 6, 1965, to be followed by a memo-[fol. 6] randum to be filed herein, in which this Court adhered to its prior decision, filed on November 17, 1964, it is hereby

Ordered, that defendants' motion for summary judgment dismissing the complaint on the grounds that the complaint fails to set forth a justiciable controversy and this is an unconsented suit against the United States is denied in all respects; and it is further

Ordered, that this Court is of the opinion that this order involves controlling questions of law as to which there is substantial ground for difference of opinion, and that an immediate appeal from this order may materially advance the ultimate termination of the litigation; and it is further

Ordered, that if defendants make timely application to the Court of Appeals for permission to appeal from this order, the proceedings in the District Court shall be stayed pending determination of such application or of the appeal, if it is allowed.

Dated: New York, New York
December 8, 1965.

Harold R. Tyler, Jr., U.S.D.J.

[fol. 7]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

63 Civ. 3349

OPINION DATED DECEMBER 10, 1965—
Filed December 13, 1965

Tyler, D.J.

Defendants (hereinafter collectively referred to as "FDA"), with the permission of this court, have made a renewed motion to dismiss the complaint and for summary judgment pursuant to F.R.C.P. 56 and 28 U.S.C. 2201 on the grounds that the complaint fails to set forth a justiciable controversy and that this is unconsented suit against the United States. In the alternative, defendants have moved for an order pursuant to the provisions of 28 U.S.C. 1292(b) certifying the aforesaid issues for an interlocutory appeal.

By way of background, the principal impetus for this renewed motion stems from recent opinions filed by the United States Courts of Appeals for the Third Circuit in *Abbott Laboratories* v. *Celebrezze, et al.*, —— F.2d ——, decided November 1, 1965, and for the District of Columbia in *The Danville Tobacco Association et al.* v. *Freeman*, —— F.2d ——, decided September 30, 1965. Both decisions, in general terms, were rulings that the district courts should have dismissed complaints for failure to state justiciable controversies where complainants were ostensibly challenging the meaning and validity of agency [fol. 8] regulations. Thus, FDA here asserts that the facts of the present case are substantially analogous to those in *Abbott* and *Danville Tobacco*, and that, therefore, the decision of this court filed on November 17, 1964 and determining, among other things, that the present case presents a justiciable controversy in a context not involving an unconsented suit against the United States, should be reconsidered and overturned.

The parties amply briefed the issues upon this renewed motion, and oral argument were heard on December 6, 1965. On December 8, 1965, this court filed an order denying the renewed motion of FDA for dismissal but certifying the questions presented for an interlocutory appeal. This memorandum is designed to sketch the principal reasons for this court's refusal to disturb its original determination filed approximately one year ago.

No useful purpose can be served here in replowing the same ground covered in the opinion of this court reported at 235 F. Supp. 648. Essentially, I do not agree with FDA's arguments that *Abbott* and *Danville Tobacco* present facts and circumstances opposite to the case at bar.*

[fol. 9] As already indicated in the earlier opinion of this court, FDA in the last analysis has consistently bottomed all of its arguments upon the technical proposition that the regulations here under attack are "interpretive" as opposed to "legislative".** This cornerstone contention of FDA, it seems to me, has several deficiencies. Preliminarily, it smacks of hypertechnicality; in the words of Chief Justice Stone, "the ultimate test of reviewability is not to be found in an over-refined technique. . .". *Columbia Broadcasting System, Inc.* v. *United States,* 316 U.S. 407, 425 (1942). More significant, this court has already found upon the allegations of the complaint in this case that FDA has promulgated final regulations pursuant to the Color Additives Amendments of 1960 enacted by Congress as part of the Food, Drug and Cosmetics Act (74 Stat. 397, Public Law 86-618, 86th Cong., 2d Session, 21 U.S.C. 321[+] and 376) (hereinafter the "Act"); that there is raised by the parties a substantial issue as to whether or not four of

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* Indeed, *Danville Tobacco* seems to me so obviously inapposite as to warrant no detailed discussion whatsoever. I suspect that FDA in part would agree because its papers and oral argument were principally keyed to *Abbott,* with little or no detailed discussion of *Danville Tobacco.*

** See discussion in 57 Yale L. J. 919, 928-9 (1948).

these final regulations significantly exceed the legislative mandate of the 1960 Amendments; and that irreparable harm would attach to plaintiffs unless these issues are resolved in this declaratory judgment action prior to piecemeal administrative litigation upon individual license applications. It is in the light of these findings that I reach my opinion that *Abbott,* and, of course, *Danville Tobacco,* are distinguishable from this case.

Granting *arguendo* that *Abbott Laboratories* is generally [fol. 10] more similar to the present controversy, it must be emphasized that there the applicable statutory provision* merely required that with respect to prescription drugs, the established or generic drug name be printed "prominently" on the label in type half as large as any brand or proprietary name. Presumably, this "prominently" requirement could be satisfied in a number of ways such as by means of a special label in large type-face, or by printing the generic name in bold red letters and the like. In its pertinent regulations, FDA in effect provided that the generic name must be shown "prominently" not only on labels but "each time" the trade name is used for any purpose, whether it be advertising, labelling or whatever. Perhaps understandably under these circumstances, the Court of Appeals ruled that the issue presented was one of interpretation of the regulations in question and, as such, not cognizable by the district court.

But the situation in this case is significantly different. Here the plaintiff contends that: (1) the 1960 Color Additive Amendments require merely pretesting, listing and certification for dyes, pigments and other color ingredients; (2) they do not change the statutory exemption for hair dyes; and (3) they do not grant FDA access to industry formulae for cosmetic products. But plaintiffs also allege that FDA has issued regulations, purportedly under the authority of the Color Additive Amendments, which would:

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* Section 502(e)(1)(B) of the Act.

(1) require pretesting, listing and certification for finished [fol. 11] cosmetic products, including hair dyes, and, as well, for the non-color ingredients of finished cosmetics; (2) change and limit the statutory exemption for hair dyes; and (3) grant FDA inspectors access to cosmetic formulae. In short, the complaint contains significant allegations of administrative regulations which rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress in the 1960 Color Additives Amendments.* Thus it is that in my opinion this case presents a different issue of "reviewability" or "justiciability" than that before the court in *Abbott Laboratories.*** Upon the complaint allegations, this is not necessarily a case where, as FDA is prone to argue, the parties are simply bickering as to how the regulations are to be interpreted and applied. Rather, on the face of the pleadings, this is a case involving allegations of serious and significant excesses by an executive agency, through the device of final regulations, beyond the powers conferred by Congress upon the agency in the 1960 Amendments. Whether or not these claims are true presents, in my view, a justiciable controversy which is ripe for determination by a district court under the Declaratory Judgment Act. [fol. 12] In reaching the latter conclusion, I am not unaware of another argument of FDA which, though not novel, takes on special focus by virtue of certain discussion of the Court of Appeals in *Abbott Laboratories.* FDA urges as a principal argument against reviewability here that Congress has provided another and more efficacious remedy for aggrieved industry members. In substance, this is the remedy of judicial review by a Court of Appeals from individual orders of the FDA upon applications for

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* For other possible distinguishing factors, see discussion of this court at 235 F. Supp. at pages 651-2.

** Moreover, even if it be said that this case is not distinguishable from *Abbott,* then I would disagree with the reasoning and ultimate result to date of the latter case.

licenses for cosmetics, all as set forth in subsection (f)(1-5) of Section 701 of the Act. Apparently, FDA obtains comfort from certain statements concerning this statutory method of review by the Court of Appeals at 8 and 9 of its slip opinion in *Abbott Laboratories*. But, as I see it, such is cold comfort indeed in view of the fact that the Court of Appeals in *Abbott Laboratories* at the threshold had determined that they were concerned with an interpretive as opposed to "legislative" regulations such as are alleged in the case at bar. Moreover, subsection (f)(6) of Section 701 of the Act underscores the Congressional intention that the special review of license proceedings by the Courts of Appeals "shall be in addition to and not in substitution for any other remedies provided by law." Finally, it is scarcely to be thought that judicial review limited to the traditional and narrow scope of whether or not the Commissioner's findings are supported by adequate evidence can supplant the other and broader form of remedy or review available under the Declaratory Judgment Act.

A brief, final paragraph may be in order respecting that part of this court's December 8, 1965 order certifying the [fol. 13] questions pursuant to 28 U.S.C. 1292(b). Aside and apart from the circumstance that plaintiffs have agreed to the FDA's request for certification, it is clear from a review of the general case law in this field that, notwithstanding my firmly held views on the issues here of justiciability and whether or not this is an unconsented suit against the sovereign, there is ample room for difference of opinion. Further to bespeak the obvious, a different view than mine would quickly terminate this litigation, which, though only commenced last year due to doubtless necessary delays in the regulation making process, involves subject matters passed upon by the Congress five years ago. Even if the reviewing court were to agree that this court has properly taken jurisdiction, it must be borne in mind that this case was ready to proceed to trial on December 6,

1965, the day when this renewed motion was argued—i.e. in the event of an unsuccessful interlocutory appeal, this case presumably can be resolved on the merits without undue additional delay.

H. R. Tyler, Jr., U.S.D.J.

December 10, 1965.

[fol. 68]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

ANSWER—January 4, 1965

Defendants, Anthony J. Celebrezze, Secretary of Health, Education and Welfare and George P. Larrick, Commissioner of Food and Drugs, by their attorney, Robert M. Morgenthau, United States Attorney for the Southern District of New York, for their answer herein:

1. Deny each and every allegation contained in Paragraph "1" of the Complaint except admit that regulations entitled "Part 8-Color Additives" were published in the Federal Register, June 22, 1963, 28 F. R. 6439.

2. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "2" of the Complaint except deny that the plaintiffs have any right to relief here in respect of and arising out of the same transaction and occurrence or that questions of law and fact common to all of them, will arise in this action.

3. Deny each and every allegation contained in Paragraph "3" of the Complaint except admit that the defendant, the Honorable Anthony J. Celebrezze, is, and was at the time the regulations in question were published, the Secretary of Health, Education and Welfare of the United States of America and that as such he was and is authorized by Section 701(a) of the Federal Food, Drug and

Cosmetic Act, 21 U.S.C. 371(a) to promulgate regulations [fol. 69] and, pursuant to Section 706(b) and (c) of said Act, 21 U.S.C. 376(b) and (c), to provide, by regulation, for the separate listing of color additives for use in food, drugs, and cosmetics and for the certification [or exemption from certification] of batches of color additives; and except that defendants further admit that the defendant, George P. Larrick, is, and was, on the date the regulations in question were published, Commissioner of Food and Drugs of the United States of America, responsible for the supervision and administration of the Food and Drug Administration, in which capacity he did sign and cause to be published the regulations of June 22, 1963, entitled "Part 8—Color Additives." For further answer to said paragraph, defendants state that the authority for the defendant, George P. Larrick, to so sign and publish such regulations is granted to him, in his capacity as Commissioner, by the Secretary of Health, Education, and Welfare, 25 F.R. 8625.

4. Deny each and every allegation contained in Paragraph "4" of the Complaint.

5. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "5" of the Complaint.

6. Deny each and every allegation contained in Paragraph "6" of the Complaint.

7. Deny each and every allegation contained in Paragraph "7" of the Complaint except admit that the synthetic colors most widely used in the food, drug and cosmetic [fol. 70] industries are chemical components which are, or could be, derived from coal-tar or coal-tar constituents.

8. Deny each and every allegation contained in Paragraph "8" of the Complaint except admit that coloring materials are manufactured by chemical and dye corporations who sell such products to food, drug, and cosmetic

manufacturers and to ingredient manufacturers serving the food, drug, and cosmetic industries.

9. Deny each and every allegation contained in Paragraph "9" of the Complaint except admit that the Secretary of Agriculture was charged with the administration of the Food and Drug Act of 1906; that the Act of 1906 did not specifically refer to cosmetics; that many color manufacturers submitted to the Department of Agriculture, pursuant to a voluntary program of certification, samples of some batches of coal-tar colors; and that, where such batches were found to be harmless, they were so certified by the Department of Agriculture.

10. Deny each and every allegation contained in Paragraph "10" of the Complaint except admit that the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, was enacted in 1938 and for the true terms and conditions thereof defendants shall refer to the official text upon the trial of this action.

11. Admit the allegations contained in Paragraphs "11", "12" and "13" of the Complaint except deny that the said quotations are complete.

[fol. 71] 12. Deny each and every allegation contained in Paragraph "14" of the Complaint and for the true terms and conditions of the said statute and regulations defendants shall refer to the official texts thereof on the trial of this action.

13. Deny each and every allegation contained in Paragraph "15" of the Complaint except admit that, pursuant to the 1938 Federal Food, Drug, and Cosmetic Act, 118 coal-tar colors were listed by the Food and Drug Administration; and except deny knowledge or information sufficient to form a belief with respect to whether or not such colors include substantially all the color additives which were added to and used in lipsticks, rouges, and nail polish enamels in excess of 95% of such cosmetics sold in the United States.

14. Deny each and every allegation contained in Paragraph "16" of the Complaint except admit that on December 15, 1958 the Supreme Court decided *Flemming* v. *Florida Citrus Exchange,* 358 U.S. 153, the true terms and conditions of which are set forth in the official reports.

15. Deny each and every allegation contained in Paragraph "17" of the Complaint except admit that the then Secretary and the Commissioner of Food and Drugs initiated a review of all listed coal-tar colors as early as 1950, as well as a scientific study of several such colors, with the result that seven basic colors were removed from the harmless list and other colors were in the process of removal from such lists when the Color Additive Amendment was passed.

[fol. 72] 16. Deny each and every allegation contained in Paragraph "18" of the Complaint.

17. Deny each and every allegation contained in Paragraph "19" of the Complaint except admit that the Secretary of Health, Education, and Welfare did support a bill before Congress which would empower the Department of Health, Education, and Welfare to establish tolerance limitations and any other needed restrictions on the use of color additives in finished products, such limitations to be based upon the principle that any color additive must be safe for its intended use before its use should be permitted which support is fully set forth in the Hearings in H.R. 7624, 86th Cong., 2d Sess. (1960), pp. 15-32, 36-105, 495-538.

18. Admit the allegations contained in Paragraph "20" of the Complaint except deny that the said quotation constituted a complete statement of the emergency.

19. Deny each and every allegation contained in Paragraph "21" of the Complaint except admit that the 1938 Federal Food, Drug, and Cosmetic Act was limited to coal-tar colors, but assert that "coal-tar" colors were defined by an administrative regulation promulgated in 1939 as "articles (1) which are composed of or contain any sub-

stance derived from coal-tar, or any substance so related in its chemical structure to a constituent of coal-tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, or cosmetic or the human body or any part thereof, are capable (alone [fol. 73] or through reaction with other substances) of imparting color thereto."

20. Deny each and every allegation contained in Paragraph "22" of the Complaint except admit that the Department of Health, Education, and Welfare favored an expansion of the color additives legislation so that it would apply to all colors, not just coal-tar colors and their derivatives.

21. Admit the allegations of Paragraph "23" of the Complaint except deny that the said quotation is complete.

22. Deny each and every allegation contained in Paragraph "24" of the Complaint except admit the accuracy of the quotation of *Part* of Section 201(t) of the Federal Food, Drug, and Cosmetic Act.

23. Deny each and every allegation contained in Paragraph "25" of the Complaint except admit that these were two of the purposes of the new legislation, the paramount purpose of which was to provide an entirely new legal mechanism for applying the safe-for-use principle to "color additives" so as to allow the use of color additives which were themselves toxic, under tolerances and other use restrictions to be established in regulations, and to apply the new law both to the color additives themselves as ingredients and to any food or cosmetic which was or which bore or contained any unapproved color additive. See Sec. 402 (c), 601(e), 21 U.S.C. 342(c) and 361(e); H.R. Rep. 1761, 86th Cong., 2d Sess., and Hearings on H.R. 7624, 86th [fol. 74] Cong., 2d Sess.

24. Deny each and every allegation contained in Paragraph "26" of the Complaint except as hereinabove specifically admitted.

25. Deny each and every allegation contained in Paragraphs "27" through "32" of the Complaint except admit

the enactment of the statutes therein referred to and for the true terms and conditions thereof defendants shall refer to the official text upon the trial of this action.

Responding specifically to paragraph 27, the defendants assert that the safe-for-use principle is incorporated in Section 706(b), 21 U.S.C. 376(b); that defendants are directed to provide for the listing of color additives only to the extent that they will be safe when employed under the conditions authorized in regulations; that such regulations, to the extent deemed necessary by the Secretary to assure safe use, may prescribe the conditions of use (including, but not limited to, specifications as to the maximum quantities which may be used or permitted to remain in or on any articles, specifications as to the manner in which such additive may be added or used, and directions and labeling and packaging requirements for such additives), Sec. 706(b)(3); that the Secretary is directed to take into account specified relevant factors in determining likely safe use, which include use and exposure data, information on the cumulative effect of any such additive and any related substance on man or animal, appropriate safety factors, and the availability of any needed practicable methods of analysis for the [fol. 75] additive or for any substance formed in or on food, drugs, or cosmetics as a result of the use of any such additive, Sec. 706(b)(5)(A); that no color additive may be approved if it has a cancer-producing potential, Sec. 706(b)(5)(B); that no color additive may be listed if the proposed use would promote deception or result in adulteration or misbranding, Sec. 706(b)(6); that no tolerance may be established unless the amount tolerated will be safe and no tolerance shall be set at a level higher than necessary to achieve the intended effect, Sec. 706(b)(7); and that the Secretary may allocate color additives among foods, drugs, and cosmetics when this is necessary to achieve safety in use, Sec. 706(b)(8).

Replying specifically to paragraph 28, defendants admit that they are directed to provide separate lists for color additives for food, drug, and cosmetic use, and that they

are to provide for certification of batches of safe color additives, with safe diluents or without diluents, or to exempt color additives from batch certification when that is not necessary for the protection of the public health.

Replying specifically to paragraph 29, the defendants assert that the "adulteration" provisions are found in Sections 402(c), 501(a)(4), and 601(e) of the Federal Food, Drug, and Cosmetic Act.

Replying specifically to paragraph 30, defendants assert that color additives may not be listed for safe use unless the scientific data available supports that conclusion, that this may necessitate the accumulation of safety data at [fol. 76] some expense, and that provisional listing was authorized during the transitional period from the coal-tar certification system to the new safe-for-use listing and certification system.

Replying specifically to paragraph 31, the 1960 Amendments provided for certain color additives to be deemed provisionally listed during this transitional period.

Replying specifically to paragraph 32, defendants admit that the provisional listing and deemed provisional listings were to continue for 2½ years, with authority in the Secretary to extend these listings upon a finding that it was reasonably safe to do so while the scientific investigations were under way, and with equal authority to terminate forthwith any provisional listing or deemed provisional listing at any time when safety could no longer be reasonably assured.

26. Admit the allegations contained in Paragraph "33" of the Complaint except that for the true terms and conditions of the said regulations defendants shall refer to the official text thereof upon the trial of this action.

27. Deny each and every allegation contained in Paragraph "34" of the Complaint except admit that the color additives then provisionally listed by the Commissioner of Food and Drugs did not include finished cosmetic products and that temporary tolerances have been prescribed as an

interim measure under the transitional provisions of the law for a group of colors in lipstick [21 C.F.R. 8.503] until [fol. 77] the proof could be developed as to the safety of the lipsticks containing a group of coal-tar colors on the deemed provisional list.

28. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "35" of the Complaint except admit that they have been advised informally about the alleged program of testing sponsored by the plaintiffs. Defendants allege affirmatively that no completed data has been submitted to them; that the defendants have not approved any color additives on the basis of such investigations; that on July 6, 1963, the defendants called upon interested persons for information about diluents, including safety data; that the last submission of information from the Toilet Goods Association was submitted with a letter dated November 20, 1964, giving the results of a questionnaire survey on the length of time certain non coal-tar colors had been used in cosmetics; and that as a result of the request for information about the use of diluents, some information has been offered by individual firms on about 60 diluents.

29. Deny each and every allegation contained in Paragraph "36" of the Complaint except admit that the two and one-half year period prescribed by the Color Additives Amendment, Sec. 203(a)(2)(A), expired on January 12, 1963 and that the closing date of colors provisionally listed was postponed under authority granted by Sec. 203(a)(2)(B), and that such provisionally listed colors constitute the class of colors which may be used in cosmetics pending the [fol. 78] issuance of permanent listings of color additives as safe for their intended uses.

30. Deny each and every allegation contained in Paragraphs "37" and "38" of the Complaint except admit the enactment of the said statute, for the true terms and conditions of which defendants shall refer to the official text upon the trial of this action.

31. Deny each and every allegation contained in Paragraphs "39" and "40" of the Complaint except admit the promulgation of the said regulations and for the true terms and conditions thereof defendants shall refer to the official text upon the trial of this action.

32. Deny each and every allegation contained in Paragraph "41" of the Complaint except admit that no color additive for cosmetic use has been listed in any current regulation published pursuant to Sec. 706(a) of the Federal Food, Drug, and Cosmetic Act; that all such color additives are on the provisional list at this time; that there is a temporary tolerance for certain coal-tar colors in lipstick; that other color cosmetics are using provisionally listed or deemed provisionally listed color components during the transitional period; that pending the outcome of this litigation, there has been no threat of enforcement against color cosmetics; and that as to finished commodities, the permanent listing regulation for food color additives include at least two articles which are finished food ingredients. §§8.301, 8.306.

33. Defendants deny each and every allegation contained [fol. 79] in Paragraph "42" of the Complaint.

34. Deny each and every allegation contained in Paragraph "43" of the Complaint except admit that the quotation appearing therein is an accurate quotation from a press release issued upon the publication of the Color Regulations in question.

35. Deny each and every allegation contained in Paragraph "44" of the Complaint.

36. Deny each and every allegation contained in Paragraph "45" except as hereinbefore specifically admitted.

37. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "46" of the Complaint except admit that requiring advance proof of safety for intended use will require plaintiff companies to reexamine established business

practices, and will have an impact on the launching and marketing of proposed new cosmetics.

38. Deny each and every allegation contained in Paragraph "47" of the Complaint except as hereinbefore specifically admitted and except that defendants deny knowledge or information sufficient to form a belief with respect to whether some of the plaintiffs are known as private brand manufacturers which make cosmetic products for other companies.

39. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained [fol. 80] in Paragraph "48" of the Complaint except deny that the Toilet Goods Association is affected by the said regulations.

40. Deny each and every allegation contained in Paragraphs "49" and "50" of the Complaint except as hereinbefore specifically admitted.

41. Deny each and every allegation contained in Paragraphs "51", "52" and "53" of the Complaint.

42. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "55" of the complaint, except admit they have certified both batches of pure coal-tar colors and coal-tar color mixtures for cosmetic use; that many pure dyes and pigments have such tinctorial strength that they must be diluted to serve as components of food, drugs, or cosmetics or as cosmetics; that diluents are used for this purpose; and that the diluents customarily used in coal-tar color mixtures were vehicles such as water, glycerine, alcohol, sugar, etc., which served to facilitate the use of the color in the food, drug, or cosmetic for which the color was intended.

43. Admit the allegations contained in Paragraph "56" of the Complaint.

44. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in

Paragraph "57" of the Complaint except admit that many [fol. 81] finished cosmetic products contain dyes, diluents, and other ingredients and that doubtless many such ingredients are purchased by the plaintiff companies from a variety of manufacturers.

45. Deny each and every allegation contained in Paragraph "58" of the Complaint except admit that the notice of proposed rule-making on the color additive regulations was published in the Federal Register on January 24, 1961, 26 F.R. 679, and that the rules were promulgated by an order published in the Federal Register on June 22, 1963, 28 F.R. 6439, and that for the true terms and conditions thereof defendants shall refer to the official texts upon the trial of this action.

46. Admit the allegations of Paragraph "59" of the Complaint.

47. Deny each and every allegation contained in Paragraphs "60", "61" and "62" of the Complaint.

48. In response to Paragraph "63" of the Complaint defendants repeat and reallege their responses to Paragraphs "45", "46", "47" and "50" of the Complaint as if here set forth at length.

49. Deny each and every allegation contained in Paragraphs "64", "65" and "66" of the Complaint.

50. Deny each and every allegation contained in Paragraph "68" of the Complaint except admit that many of the plaintiff companies are engaged in the manufacture, distribution, and sale in interstate commerce of finished cosmetic products which are used for coloring the hair; that [fol. 82] hair dye products contain other ingredients than coal-tar color and dyes; that some hair dye products manufactured and sold by various of the plaintiff companies do not contain any coal-tar colors; that such products, such as tinting shampoos, do color the hair and such products do have potentials for harmful effects other than those caused by sensitization, including such reactions as cirrhosis of the liver or nephritis of the kidneys.

51. Deny each and every allegation contained in Paragraph "69" of the Complaint except admit the accuracy of the statutory quotation contained therein.

52. Deny each and every allegation contained in Paragraph "70" of the Complaint except admit the enactment of the said statute for the true terms and provisions of which defendants shall refer to the official text on the trial of this action.

53. Deny each and every allegation contained in Paragraphs "71" through "76" of the Complaint except admit that the Commissioner issued regulations under the 1938 Act; that the FDA has from time to time suggested legislation to amend the Act; that Section 602(e) was added to the Act by the Color Additive Amendments; and that for the true terms and provisions of such regulations and statutes defendants shall refer to the official texts thereof on the trial of this action.

54. Deny each and every allegation contained in Paragraphs "77" and "78" of the Complaint except admit that on October 3, 1963, there were published, at 28 F.R. 10638, [fol. 83] regulations which omitted the definition of hair dye previously published in other regulations.

55. Deny each and every allegation contained in Paragraph "79" of the Complaint except admit that defendant Larrick issued a press release dated June 22, 1963; stated that hair coloring products that did not cause a reaction with the patch test must now be demonstrated safe before they can be marketed; and that a press release was issued October 3, 1963, which contained the statements quoted in said Paragraph "79" of the Complaint.

56. Deny each and every allegation contained in Paragraph "80" of the Complaint.

57. In response to Paragraph "81" of the Complaint defendants repeat and reallege their responses to Paragraphs "45", "46", "47" and "50" of the Complaint as if

here set forth at length and otherwise deny each and every allegation contained in said Paragraph "81".

58. Deny each and every allegation contained in Paragraph "82" of the Complaint.

59. Admit each and every allegation contained in Paragraphs "84", "85" and "86" of the Complaint, except deny that the Act prescribes any mandatory penalty for refusal to permit factory inspection and allege that no precautions of cosmetic manufacturers have ever been recommended to the Department of Justice under this section of the statute.

60. Deny each and every allegation contained in Para- [fol. 84] graph "87" of the Complaint.

61. Deny each and every allegation contained in Paragraph "88" of the Complaint except admit the accuracy of the quotation contained therein.

62. Deny each and every allegation contained in Paragraph "89" of the Complaint except that the Color Regulations contain definitions of "color additive" and "diluents" and for the true terms and provisions of such regulations, defendants will refer to the official text upon the trial of this action.

63. Deny each and every allegation contained in Paragraph "90" of the Complaint.

64. Deny each and every allegation contained in Paragraph "91" of the Complaint except admit that defendant Larrick, in a press release announcing the Color Regulations, made the statement attributed to him in the said Paragraph.

65. Deny each and every allegation contained in Paragraph "92" of the Complaint.

66. Deny knowledge or information sufficient to form a belief with respect to each and every allegation contained in Paragraph "93" of the Complaint.

67. Deny each and every allegation contained in Paragraph "94" of the Complaint.

[fol. 85]

As and for a First Separate Defense Defendants Allege:

68. The Complaint fails to state a claim against these defendants upon which relief can be granted.

As and for a Second Separate Defense Defendants Allege:

69. This Court lacks jurisdiction over the subject matter.

As and for a Third Separate Defense Defendants Allege:

70. Plaintiffs have failed to join an indispensable party, to wit, the Attorney General of the United States.

As and for a Fourth Separate Defense Defendants Allege:

71. This is an unconsented suit against the United States and, therefore, the Court lacks jurisdiction over the person of the defendants.

As and for a Fifth Separate Defense Defendants Allege:

72. Plaintiff, The Toilet Association, Inc., has no standing to sue.

[fol. 86]

As and for a Sixth Separate Defense Defendants Allege:

73. As to 27 of the plaintiff corporations, incorporated in states other than the State of New York, venue is improperly laid in the Southern District of New York.

As and for a Seventh Separate Defense Defendants Allege:

74. The Complaint fails to allege a case of actual controversy within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201.

As and for an Eighth Separate Defense Defendants Allege:

75. The Regulations here at issue are, in all respects, in accordance with the provisions of the Federal Food,

[fol. 87] Drug and Cosmetic Act and in no way exceed any authority granted thereby.

Dated: New York, New York, January 4, 1965.

Robert M. Morgenthau, United States Attorney for the Southern District of New York, Attorneys for Defendants, By: Arthur S. Olick, Assistant U.S. Attorney, Office & P.O. Address: United States Courthouse, Foley Square, New York, New York, 10007, CO 7-7100, ext. 319.

To: Breed, Abbott & Morgan, Esqs., Attorneys for Plaintiffs, 1 Chase Manhattan Plaza, New York, New York, 10005.

[fol. 88]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

63 Civ. 3349

Breed, Abbott & Morgan, of New York, N.Y., Attorney for Plaintiff, William L. Hanaway, Esq., Edward J. Ross, Esq., and Stephen R. Lang, Esq., of Counsel.

Robert M. Morgenthau, United States Attorney, Attorney for Defendants, by Arthur S. Olick and Patricia A. Garfinkel, Assistant United States Attorneys, and William W. Goodrich, Assistant General Counsel for Food & Drugs, and William R. Pendergast, Esq., Attorney, United States Department of Health, Education & Welfare.

OPINION DATED NOVEMBER 16, 1964—Filed November 17, 1964.

TYLER, D.J.

Forty individuals and companies manufacturing, distributing, and selling cosmetics in interstate commerce and

an association of cosmetic manufacturers here seek a declaratory judgment [28 U.S.C. § 2201] as to the validity of certain provisions of regulations promulgated by the Commissioner of the Food and Drug Administration (FDA). These regulations were issued pursuant to the 1960 Color Additives Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-81.* More specifically, plaintiffs con- [fol. 89] tend that the challenged regulations exceed the authority vested in the FDA by the statute, as amended, and pray that the Court declare the regulations null and void and enjoin their enforcement.

Essentially, the 1960 Amendments expand the Act's provisions for the pretesting of coal tar colors to require the pretesting of all color additives, irrespective of their derivation. To this end, the term "color additive" is defined as "a dye, pigment, or other substance" which, "when added or supplied to a food, drug or cosmetic, or to the human body or any part thereof, is capable . . . of imparting color thereto." 21 U.S.C. § 321(t)(1). The Amendments further state that color additives shall be deemed "unsafe" within the meaning of the Act unless they conform to regulations for the listing of additives and for "the certification, with safe diluents or without diluents, of batches of color additives." 21 U.S.C. § 376.

To implement these Amendments, the Commissioner of the FDA issued the Color Additives Regulations, dated June 13, 1963.** 28 F.R. 6439, 21 C.F.R. §§ 8.1-8.6003. Those provisions of the regulations here challenged as in excess of the statutory authority on which they purport to be based are:

[fol. 90] (a) provisions of Section 8.1(f) which, it is claimed, may have the effect of defining a color additive

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* The Amendments were enacted on July 12, 1960.

** Actually, 21 U.S.C. § 371(a) vests in the Secretary of the Department of Health, Education and Welfare the authority to promulgate Food & Drug Act regulations. Defendants' memoranda explain that the responsibility for their actual promulgation was delegated to the Commissioner.

as including finished cosmetic products, and consequently, of requiring the pre-testing of finished products;

(b) provisions of Sections 8.1(f) and (m) which define color additives as including all diluents and which, plaintiffs claim, may require the pre-testing, listing and certification of all ingredients of cosmetics containing a color additive mixture;

(c) provisions of Section 8.1(f) and (u) which are claimed to make nugatory any statutory exemption for hair dyes, 21 U.S.C. § 361(a) and (e); and

(d) provisions of Section 8.28(a)(4) which plaintiffs contend is an unwarranted grant of access by FDA investigators to all processes and formulae involved in the manufacture of cosmetics.

Defendants have moved for an order dismissing the complaint, and, alternatively, for an order "striking certain portions of the complaint." *

I.

Defendants' principal contention on their motion to dismiss is that the complaint fails to state a case of actual controversy, as required by the Declaratory Judgment Act, 28 U.S.C. § 2201, particularly because of the absence of any [fol. 91] threatened or attempted enforcement of the regulations.

Although the Declaratory Judgment Act was never intended or construed to grant the federal courts license to render advisory opinions, threatened enforcement of a statute or administrative regulation is not a *sine qua non* for its review under the Act. See *Borchard, Declaratory Judgments* (2d ed., pp. 365-6). In *Columbia Broadcasting System, Inc.* v. *United States*, 316 U.S. 407, 417-18 (1942), FCC regulations provided that radio stations would have their licenses revoked if they entered into contracts with

* Defendants, however, have not specified which portions they wish stricken.

networks containing certain prohibited clauses. The court held the regulations to be reviewable because of their serious impact upon the radio network's ability to conduct its business and stated that, "If an administrative order has that effect it is reviewable and it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty incurred under its regulations for noncompliance."

Recently, in *Abbott Laboratories* v. *Celebrezze*, 228 F. Supp. 855 (D. Del. 1964), where drug manufacturers challenged FDA labeling regulations, Chief Judge Wright held, at page 861:

> "Plaintiffs may have judicial review of interpretive regulations upon their promulgation without awaiting some ultimate enforcement. *Frozen Food Express* v. *United States*, 351 U.S. 40, 76 S. Ct. 569, 100 L.Ed. 910 (1956); *Federal Trade Commission* v. *Nash-Finch Company*, 110 U.S. App. D.C. 5, 288 F.2d 407. They [fol. 92] need not await an action which would only make the threat of harm more pressing."

Thus, while the threat of enforcement is often present in cases where the courts have taken jurisdiction and rendered a declaratory judgment on the validity of a challenged regulation or statute, the existence of such a threat merely serves as some evidence indicating the presence of an actual controversy and that the plaintiff stands to suffer "real, immediate and incalculable" harm. See concurring opinion of Mr. Justice Douglas, *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U.S. 123, 175 (1951).

In *Maryland Casualty Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1940), the Supreme Court said that, "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

More specifically, as to the reviewability of administrative rulings, Chief Justice Stone said in *Columbia Broadcasting System, Inc.* v. *United States, supra,* at page 425:

> "The ultimate test of reviewability is not to be found in an overrefined technique, but in the need of the review to protect from the irreparable injury threatened in the exceptional case of administrative rulings which attach legal consequences to action taken in advance of other hearings and adjudications that may [fol. 93] follow, the results of which the regulations purport to control."

This being the test, I find it difficult and indeed inappropriate, at least under the circumstances here presented, to resolve the issue of reviewability upon the technical distinction, pressed by defendants, between legislative and interpretive regulations. Parenthetically, I should add that I read no federal authority to precisely support the defendants' argument that the regulations here involved are "interpretive" as opposed to "legislative" and thus do not "approach a degree of finality such as would warrant access to the Courts". (See page 59 et seq. of the government's principal brief).*

In any event, for reasons to be discussed hereinafter, I conclude that in a substantial and practical business sense plaintiffs are threatened with irreparable injury by the obviously intended consequences of the challenged regulations, and that to resort to later piecemeal resolution of the controversy in the context of individual enforcement proceedings would be costly and inefficient, not only for the plaintiffs but as well for the public as represented by the defendants.

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* In fairness to defendants, however, it must be said that some commentators and courts have discussed this distinction in theoretical terms. See Davis, *Administrative Rules—Interpretative, Legislative and Retroactive,* and cases therein cited. 57 Yale L. J. 919, 928-29 (1948).

The regulations force manufacturers to choose between [fol. 94] complying with them, at a cost that may prove to be prohibitive for some of the plaintiffs, or ignoring them at the risk of incurring the statutory penalties should the regulations later be held valid. And, as Chief Judge Wright recently observed in the *Abbott Laboratories* case, *supra,* at 862: "The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril."

An affidavit submitted on behalf of one of the plaintiffs asserts that the cost of compliance to this plaintiff alone will be over $50,000,000. While this amount is immediately suspect,* there can be little doubt but that the added recordskeeping and laboratory testing costs in themselves will be extremely burdensome for all of the plaintiffs.

Aside from such measurable out-of-pocket costs of compliance, it is not difficult to perceive that the impact of the regulations on plaintiffs' present methods of doing business will be substantial and will give rise almost certainly to potentially greater expenses. That the latter are "hidden expenses" in the sense that they are presently incalculable does not diminish their significance. For ex- [fol. 95] ample, in the area of research alone, plaintiffs' affidavits show that the provisions of the regulations dealing with listing and with access to all formulae and processes will have an immediate adverse effect upon further research and development of new products. The situation here, incidentally, contrasts sharply with the facts of *Helco* v. *McNutt,* 137 F.2d 681 (D.C. Cir. 1943), where the plaintiff sought a declaratory judgment on the validity of a simple advisory opinion of the FDA elicited in response to the plaintiff's inquiry whether or not its proposed busi-

* The affiant apparently confused § 8.50(c) of the regulations, which requires a *deposit* of $2,600 for each listing application, with § 8.50(j), which establishes a *fee* of $250 "for services in listing a diluent" for use in color additive mixtures.

ness venture would violate the Food and Drug Act. Rather, we are dealing with a case that more closely parallels *Wallace* v. *Currin*, 95 F.2d 856 (4th Cir. 1938), *aff'd.*, 306 U.S. 1 (1939). The court in that case held that the plaintiffs, tobacco warehousemen, could challenge the 1955 Tobacco Inspection Act in a declaratory judgment suit because of the Act's substantial interference with their businesses, notwithstanding the fact that the cost of compliance for each warehouseman would only be $25 per marketing season.

Having established that a justiciable controversy exists, there are at least two compelling reasons for assuming jurisdiction and determining in this action the validity of the challenged regulations.

First, since a concern for consumer safety is ostensibly the principal motive underlying promulgation of the Color Additives Regulations, there is a strong public interest in an early determination of their validity. Four years have already elapsed since Congress enacted the statutory pro- [fol. 96] visions which the regulations seek to implement. Any further delay in determining whether or not the cosmetic industry need comply with the regulations will only serve to further frustrate Congress' purpose of providing the consuming public with protection against potentially harmful color additives.

Second, this action provides an opportunity to examine all four challenged regulatory provisions together within the context of a single plenary proceeding. Since these four provisions are interrelated as elements of a common plan of governmental regulation, there is a distinct advantage in reviewing them together. Moreover, since the regulations raise complicated and technical issues which will require expert testimony to resolve—undoubtedly from many of the same witnesses—there is a practical advantage for the litigants as well as for the court in having this testimony brought forth in a single action rather than in four or more separate suits or enforcement proceedings.

II.

Since I conclude that there is a justiciable controversy presented and further that it would be improvident to decline jurisdiction on discretionary grounds, this would dispose of the dismissal motion were it not for the fact that defendants raise two further arguments for dismissal of the entire action and two other arguments for dismissal as to certain of the plaintiffs. All four issues so raised must be resolved against defendants, at least at this stage [fol. 97] of the proceedings:

(1) This is not an unconsented suit against the United States. Keeping in mind the distinction drawn in *Larson* v. *Domestic & Foreign Commerce Corp.*, 337 U.S. 682 (1949), the thrust of the claim here is not that the Commissioner wrongly exercised his delegated powers—which would be a claim against the sovereign—but that he acted in excess of his statutory authority and therefore outside the scope of his delegated powers. And, as the Supreme Court said in *Larson*, at 689, "where the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions." See *Abbott Laboratories* v. *Celebrezze, supra; Philadelphia Company* v. *Stimson*, 223 U.S. 605 (1912); *Federal Trade Commission* v. *Nash-Finch Company*, 288 F.2d 407 (D.C. Cir. 1961).

(2) The Attorney General is not an indispensable party to this action. This was the conclusion in the *Abbott Laboratories* case where the court said at page 862: "The decree sought here does not operate against the Attorney General except in a secondary fashion. He will not be forced to do anything no matter how the court decides."

(3) The Toilet Goods Association does have standing to sue. The members of the Association account for more than 90% of the annual sales of cosmetics in the United States. They are individually harmed and the Association, as a proper representative of the interests of its members,

can challenge the regulations in that capacity. *National Motor Freight Association* v. *United States*, 372 U.S. 246 [fol. 98] (1963); *Abbott Laboratories* v. *Celebrezze*, *supra*,

(4) Venue, predicated upon 28 U.S.C. § 1391(c), is proper as to each of the individually named plaintiffs. Although not all the Circuits agree, this Circuit has consistently held that 28 U.S.C. § 1391(c) applies to plaintiff and defendant corporations alike. *Freiday* v. *Cowdin*, 83 F. Supp. 516 (S.D.N.Y. 1949); *Southern Paperboard Corporation* v. *United States*, 127 F. Supp. 649 (S.D.N.Y. 1955); *Wear-Ever Aluminum Inc.* v. *Sipos*, 184 F. Supp. 364 (S.D.N.Y. 1960).

Accordingly, defendants' motion to dismiss is denied in all respects.

III.

Since the papers already submitted by the parties raise substantive issues outside this court's ordinary sphere of competence, it would be unwise to make a determination on the merits at this stage without the aid of "live", expert testimony.

To be sure, the essential questions presented in this action are ones of statutory interpretation; whatever competence the court and counsel may have in this area generally, however, can only be enhanced by a particular understanding, to be obtained with expert assistance, of the technical problems involved. Additionally, since professionally qualified representatives of both plaintiffs and defendants were present during the hearings and debates which preceded the passage of the 1960 Color Additives Amendments, it would be helpful to hear their testimony relative to legislative intent, which, presumably, they had an important role in shaping and assisting.

[fol. 99] Plaintiffs' motion for summary judgment, therefore is denied.

IV.

Inasmuch as defendants have not specified what they wish to have stricken from the complaint, their motion to strike is denied.

Settle order accordingly.

Dated: New York, N. Y.,
November 16, 1964.

H. R. Tyler, Jr., U.S.D.J.

[fol. 100]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

DEFENDANTS' RENEWED MOTION TO DISMISS AND FOR SUMMARY JUDGMENT—November 18, 1965

Sirs:

Please Take Notice that upon the complaint and answer heretofore filed herein, the annexed affidavit of Arthur S. Olick, Assistant United States Attorney, sworn to the 18th day of November, 1965, the memorandum of law served and filed herewith, and upon the Regulations for Color Additives promulgated under the Federal Food, Drug & Cosmetic Act as published in Part 8, Title 21, Code of Federal Regulations, the undersigned will move this Court in Room 2603, United States Court House, Foley Square, New York, N.Y., on the 24th day of November, 1965, at 4:00 o'clock in the afternoon of that day, or as soon thereafter as counsel may be heard, for summary judgment pursuant to F. R. Civ. Proc. 56 and Title 28, United States Code, § 2201 on the grounds that (a) the complaint fails to set forth a justiciable controversy and (b) this is an unconsented suit against the United States, or, alternatively, for an order pursuant to Title 28, United States Code, § 1292(b), certifying the said issues for an interlocutory appeal, and for such other and further relief as

[fol. 101] to the Court may seem just and proper in the premises.

Dated: New York, N.Y., November 18, 1965.

Yours, etc.

Robert M. Morgenthau, United States Attorney for the Southern District of New York, Attorney for the Defendants, By Arthur S. Olick, Assistant United States Attorney, Office & P.O. Address: United States Court House, Foley Square, New York, N. Y. 10007, Tel: 264-6319.

To: Messrs. Breed, Abbott & Morgan, Attorneys for Plaintiffs, 1 Chase Manhattan Plaza, New York, N. Y. 10005.

[fol. 102]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

AFFIDAVIT IN SUPPORT OF DEFENDANTS' RENEWED MOTION TO DISMISS AND FOR SUMMARY JUDGMENT

State of New York,
County of New York, ss.:

Arthur S. Olick, being duly sworn, deposes and says:

1. I am an Assistant United States Attorney in the office of Robert M. Morgenthau, United States Attorney for the Southern District of New York, attorney for the defendants in the above entitled action. As such, I am in charge of the defense of this action, and am fully familiar with the pleadings and proceedings heretofore had herein.

2. I submit this affidavit in support of defendants' renewed motion to dismiss the complaint for failure to state a claim or, alternatively, for leave to prosecute an interlocutory appeal.

3. The Government renews its motion to dismiss the complaint on the grounds that (a) it fails to set forth a justiciable case or controversy; and (b) that this is an uncontested suit against the United States. A previous motion by the defendants on these very same grounds, among others, was denied by this Court in an opinion filed on November 17, 1964. This was just one year ago.

[fol. 103] 4. In this action virtually the entire cosmetics industry, together with its trade association, has joined together to attack the so-called "color additive amendments" to the Federal Food, Drug & Cosmetic Act. The gravamen of the complaint is that the challenged regulations exceed the authority vested in the Food & Drug Administration by this statute. Plaintiffs ask this Court to declare the regulations null and void and to enjoin their enforcement despite the fact that plaintiffs have never sought to comply with the regulations and the Government has done nothing to enforce them against any particular company.

5. Since the Court denied the Government's initial motion, two things of significance have transpired which warrant reconsideration of the issue of justiciability. First, and most important, the United States Court of Appeals for the Third Circuit has rendered a decision in a case so substantially similar to that at bar as to be virtually determinative of this issue. In *Abbott Laboratories* v. *Celebrezze*, decided on November 1, 1965, the Third Circuit held that a group of pharmaceutical manufacturers and their trade association could not attack the validity of Food & Drug Administration regulations issued pursuant to the so-called drug amendments of 1962 to the Food, Drug & Cosmetic Act because of Congress' policy of limiting prior judicial review of administrative actions under this statute and because of the absence of an actual case or controversy required for justiciability under the Declaratory Judgments Act. A copy of the Court's opinion is annexed hereto [fol. 104] as Exhibit "A". In so holding, the Third Circuit reversed the Delaware District Court whose opinion was

relied upon by the plaintiffs in this case and by this Court in connection with the prior motion. Also significant, is the decision of the United States Court of Appeals for the District of Columbia in *Danville Tobacco Assn.* v. *Freeman*, decided on September 30, 1965. A copy of the *Danville Tobacco* decision is annexed herewith as Exhibit "B". There, the Court of Appeals chastised the District Court for considering the merits of a claim by tobacco warehousemen and their trade associations that the Secretary of Agriculture's regulations adopted under the Tobacco Inspection Act and the Commodity Credit Corporation Act were invalid. The District Court held that the regulations were valid and entered judgment for the defendant Secretary of Agriculture dismissing the complaint. The Court of Appeals modified and affirmed on the grounds that the District Court should have dismissed the complaint for failure to state a justiciable issue.

Finally, since this Court's initial decision on justiciability, the parties have conducted extensive pretrial discovery and have sought to conclude an appropriate pretrial order preparatory to a trial on the merits. This has proved exceedingly difficult since the parties cannot agree on the meaning of the subject regulations and the manner in which they are apt to be enforced. For all of these reasons, as more fully set forth in the memorandum of law accompanying this motion, deponent respectfully asks that the Court reconsider its prior determination and dismiss the com-
[fol. 105] plaint for failure to state a claim.

6. In the event that this Court adheres to its prior determination, defendants request that the Court include in its order denying this motion the statement required by Title 28, U.S.C., Section 1292(b), to the effect that such holding involves "a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation . . . ". In other words, defendants ask leave to prosecute an interlocutory

appeal. Deponent submits that there is considerable doubt with respect to whether this case can properly be tried. It may well be that plaintiffs' attack on the color additive regulations is premature. If so, a finding to that effect by the Court of Appeals will obviate the necessity for a trial and thereby foreshorten the ultimate termination of this litigation. In the circumstances of this case, to subject the parties to what will unquestionably be a long, costly and difficult trial, is to impose upon them a possibly unnecessary and clearly onerous burden. The issue of justiciability is such that it must ultimately be determined by the Court of Appeals. Certainly, justice requires an appellate review of this issue before the parties are subjected to a plenary trial. It is already apparent from the proposed pretrial order in this case that numerous documents will be introduced at a plenary trial and that some 19 witnesses may be called. Moreover, the parties have encountered considerable difficulty in agreeing on the precise issues presented for adjudication on the merits.

[fol. 106] Wherefore, deponent respectfully prays that defendants' motion for summary judgment be granted and that the complaint herein be dismissed.

Arthur S. Olick, Assistant United States Attorney.

(Sworn to November 18, 1965.)

[fol. 122]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

AFFIDAVIT OF EDWARD J. ROSS—Dated November 23, 1965

State of New York,
County of New York, ss.:

Edward J. Ross, being duly sworn, deposes and says:

1. I am a member of Breed, Abbott & Morgan, attorneys for all plaintiffs herein, and am in charge of this action.

2. Plaintiffs' opposing memorandum shows that *Abbott Laboratories* v. *Celebrezze* and *Danville Tobacco Assn.* v. *Freeman* do not provide any basis for this Court's changing its decision that the Color Additives Regulations (the "Regulations") are subject to judicial review.

3. The purpose of this affidavit is to set before the Court in proper form certain documents and testimony before trial by officials of the Food and Drug Administration ("FDA"), which establish the immediate and substantial impact of the Regulations on the entire cosmetic industry, and show that they are legislative, and to correct certain misstatements in the affidavit of Arthur S. Olick, sworn to November 18, 1965 (the "Olick affidavit").

A. *Premarketing Clearance of All Finished Cosmetic Products Which Color the Body*

[fol. 123] 4. The Olick affidavit, in seeking to show that there may be no controversy because "Plaintiffs' attack on the color additive regulations is premature" (Para. 6), states that "the parties cannot agree on the meaning of the subject regulations and the manner in which they are apt to be enforced" (Para. 5).

5. *The parties are not in disagreement as to the meaning of the Regulations.* This action does not involve any issue as to their proper interpretation. Plaintiffs have accepted, for purposes of this case, both the plain language of the Regulations *and* the statements by FDA officials in press releases and in depositions as to the scope and effect of the Regulations.

6. There is no dispute that the Regulations require pretesting, listing and certification of *substantially all finished cosmetic products*, including those generally recognized as safe; that the Regulations require pretesting, listing and certification of all, or substantially all, the ingredients of such cosmetics; that the Regulations require

pretesting, listing and certification of hair dye products previously exempt; and that the Regulations give FDA inspectors access to the formulae of finished cosmetic products. This is all made abundantly clear from the Regulations, FDA releases, defendants' answers to interrogatories, and the testimony of Mr. Harvey and other FDA officials.

7. The Regulations state (§ 8.1(f)):

> "Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are [fol. 124] 'color additives'."

8. By defining a "color additive" to include finished products, and by requiring the pretesting, listing and certification of such products, the Regulations impose a comprehensive system of premarketing clearance *on all finished cosmetic products which color the body.* This was stated in the FDA release, dated June 22, 1963 (Exh. A hereto), announcing the Regulations:

> "Under the new regulations, FDA will require that an entire product—not just the color ingredient—be shown by the manufacturer to be safe before it is released for sale."

That release also described the provision for the premarketing clearance of the "entire product" as being a "new requirement," and noted that prior to the Regulations "only color * * * ingredients had been subject to the requirement for pre-marketing proof of safety."

9. Mr. Harvey testified that such release very clearly advised industry that the entire cosmetic must now be cleared in advance by FDA (Tr. pp. 309-10):

> "Q. Now, isn't that a fact that this is a very plain and very clear statement that from the issuance of the regulations, the entire cosmetic products must be shown safe before it may be released for sale? A.

The cosmetic product for applying color to the human body—

[fol. 125] "Q. Yes. A. Yes.

"Q. It was very plainly stated in this press release, was it not? A. Yes, I think it is plain.

"Q. And industry had no doubt as to what was meant by it; is that correct? A. I can more accurately report my own view that I can that of industry. It does seem clear.

"Q. And is this what is meant by the term 'pre-marketing clearance of cosmetics'? A. Yes, I think that is true, to the extent that this refers to certification or clearance of certain cosmetics, it would be a pre-marketing clearance of cosmetics, which also happened to be color additives."

10. That this is still FDA's official position is evident from defendants' answers to interrogatories, dated October 29, 1965, sworn to by William W. Goodrich, Assistant General Counsel for FDA. Interrogatory 10 asked defendants to—

"Specify the finished cosmetic products which FDA contends are required to be pretested, listed and certified, under the provisions of the Color Amendments and the Color Regulations."

Defendants' answer states:

"Any cosmetic intended to impart color to the human body would have to be listed as safe for its intended use before it could be used."

Mr. Harvey's testimony confirms this (Tr. p. 310):

"Q. And under your view, or the view of the FDA, [fol. 126] any cosmetic which imparts a color to the body is a color additive? A. That's right, *would require listing.*"

11. Mr. Harvey also made it clear that in order to obtain listing, the Regulations require "full reports of adequate tests," including "detailed data derived from appropriate animal and other biological experiments" (Tr. p. 413). He agreed such testing and detailed information would "be required in connection with applications for listing rouge, leg applications, pancake makeup," and all other finished cosmetic products which color the body (Tr. pp. 413-14).

12. The enormous burden and cost imposed by the Regulations on the cosmetic industry, particularly with respect to the testing and listing of every finished cosmetic product which colors the body, was illustrated in the affidavit of Charles R. Kircher, sworn to March 25, 1965, in support of plaintiffs' summary judgment motion. As there noted, the cost of complying with the Regulations "would be so prohibitive, it would substantially destroy Kolmar's entire domestic cosmetic business." A similar fate would be decreed for many other plaintiffs.

B. *Premarketing Clearance of Cosmetics Which Do Not Color the Body and Substantially All Their Non-Color Ingredients*

13. The Regulations also require premarketing clearance, including pretesting, listing and certification, of all [fol. 127] finished cosmetic products which contain a color, even if they do not impart color to the body. This would catch substantially all cosmetics.

The Regulations define "color additives" to include "all diluents" (§ 8.1(f)). They then define "diluent" as "any component of a color additive mixture * * * intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body" (§ 8.1(m)). *Since essentially every ingredient facilitates the use of the color, substantially all the non-color ingredients of all finished cosmetic products which contain a color would also be subject to premarketing clearance.*

14. This was made clear by David J. Miller, principal draftsman of the Regulations (Tr. p. 39):

> "Q. Let me understand this, Mr. Miller. Under the Color Regulations is 'diluent' in effect defined to include every ingredient of every cosmetic product that contains a color? A. I would say essentially yes."

* * * * * * *

15. Thus, not only do the Regulations require premarketing clearance of all finished cosmetic products which impart color, but also those cosmetics which contain a color and essentially all the non-color ingredients of such cosmetics. In fact, when Mr. Miller was asked to state those cosmetics which would not be covered by the Regulations, he could only specify "a cold cream containing no color whatsoever" (Tr. p. 41). However, since the Act defines "white" as a "color" (§ 201 (t)(2)), even cold cream [fol. 128] could be covered by the Regulations.

C. *Repeal of the Statutory Exemption For Hair Dye Products*

16. Section 601(a) and (e) of the Act contain an across-the-board exemption for hair dye products, subject to the statutory label required by Section 601(a). The Regulations change such exemption in two ways:

First, by defining a color additive to include "Lipstick, rouge, eye makeup colors and *related cosmetics intended for coloring the human body*" (§ 8.1(f)), the Regulations place hair dye products in the same category as all other cosmetics which color the body, and require the same premarketing clearance for such hair dye products.

Second, the Regulations expressly limit the exemption in Section 601(a) of the Act to hair dye products whose sole potential adverse effect is skin sensitization. According to the Regulations (§ 8.1(u)), "the exemption does not apply" to all the hair dye products.

17. Accordingly, the FDA release (Exh. A) accompanying the Regulations states:

> "The patch testing requirement offers no protection from other types of toxicity, Commissioner Larrick said, and the purpose of the new regulation is to close this gap. *Hair dyes that do not cause a reaction with the patch test must now be demonstrated to be safe before they can be marketed.*"

[fol. 129] 18. A subsequent FDA release, dated October 3, 1963 (Exh. B), candidly describes the Regulations as "limiting the exemption for hair dyes under the Federal Food, Drug, and Cosmetic Act." What better example of a "legislative" regulation than one which admittedly changes a statutory exemption?

19. The October 3, 1963 release (Exh. B) also shows the immediate effect of the Regulations. With respect "to new hair dye formulations coming on the market," the release states the regulation "applies immediately." "Products currently being marketed will not be affected until June 22, 1965."

20. The fundamental change in the statutory provisions relating to hair dye products is underscored by Mr. Harvey's testimony as to the practice prior to the Regulations (Tr. pp. 88-9):

> "Q. Then is it your testimony that assuming a hair dye product contained the statutory label, hair dye products were totally exempt from the Act; is that correct? A. Well, they were not required to be certified if they met those specifications, yes.
>
> "Q. They were not required to be listed? A. That's right.
>
> "Q. And assuming that the hair dye product and its coal-tar ingredient were neither listed nor certified, was it not a fact that the hair dye was also exempt from the provisions of Section 601(a) of the Act, if

it bore the statutory label? A. Well, I believe it was so held at one time, counselor, yes.

[fol. 130] "Q. And at which time was that, which period would that be? A. So far as I am concerned, I had that view, oh, up to perhaps a year ago, something like that."

21. Not only do the Regulations now require listing and certification of finished hair dye products, but they also require the pretesting, listing and certification of all the non-color ingredients of such products.

Accordingly, though Congress has granted an exemption for all hair dye products which bear the statutory label, in effect since 1938, the Regulations seek to repeal such exemptions and to plug what FDA calls a "gap" in the law. The substantial and practical impact on plaintiffs, as well as the "legislative" nature of the Regulations, are self-evident.

22. It could hardly be clearer from the testimony of Mr. Harvey and other FDA officials, from the FDA releases, and from the language of the Regulations themselves, that industry is now required by the Regulations to obtain FDA clearance for substantially every cosmetic marketed today, including all hair dye products, as well as the separate ingredients of such cosmetics. There is no difference of interpretation as to this requirement, and FDA cannot avoid determination of whether such requirement exceeds its statutory authority by now suggesting the Regulations are not clear, and "the parties cannot agree on the meaning of the subject regulations" (Olick Aff., Para. 5).

[fol. 131] 23. The Olick affidavit also states that because of the alleged uncertainty of the Regulations it has been "exceedingly difficult" for the parties to "conclude an appropriate pretrial order" (Para. 5). This is not my understanding. I submitted to Mr. Olick a proposed pretrial order on September 2, 1965, and I received his comments on September 27 and October 7, 1965. On October 20, 1965,

we conferred with the Court in Chambers to resolve the differences, and agreed on a format. On October 25, 1965, I sent Mr. Olick a copy of the revised pretrial order, which reflected the format as agreed upon between counsel and the Court. I never received any objections. On the contrary, I understood from Mr. Olick that the pretrial order was satisfactory. The reason it has not been presented to this Court for signature is because of the postponement of the trial until disposition of this renewed motion to dismiss.

D. *Bills For The Premarketing Clearance Of Cosmetics*

24. Plaintiffs' original memorandum (pp. 61-65), dated April 10, 1964, noted that whenever the Act requires premarketing clearance of a finished product or of ingredients on a broad basis, there is an exception for those products or ingredients which are generally recognized as safe for use. This same practice was followed in the many bills introduced over the years for the premarketing clearance of cosmetics. (Copies of three such bills are annexed hereto as Exhibit C.) Even H.R. 6788 and H.R. 11582,—bills which Mr. Ellenbogen testified were prepared and spon- [fol. 132] sored by HEW (Tr. pp. 276-7),—expressly exclude cosmetics which are generally recognized as safe for use.

25. Thus, the Regulations are even more sweeping in scope and coverage than any of the cosmetic bills which Congress has rejected. The Regulations do not exclude cosmetics which are generally recognized as safe for use, but require all cosmetics, even if safely used for 50 years or more, to be subject to the same premarket procedures as a new cosmetic formulation.

26. Significantly, both H.R. 6788 and H.R. 11582 were introduced after enactment of the Color Additive Amendments of 1960. Mr. Ellenbogen testified that cosmetic legislation was needed in order "to complete the protection of the consumer with respect to pre-marketing of cosmetics

• • • [since] the Color Additives Provision did not cover them all" (Tr. pp. 300-301). However, when asked to name any cosmetic which FDA did not consider already "covered by the Color Additive Amendments of 1960," he did not "know of any" and could not "name any offhand" (Tr. pp. 301-302). He was "not sure" whether all toothpastes were covered (Tr. p. 302).

27. Finally, Mr. Ellenbogen's testimony shows the anomaly of the Regulations since, under FDA's view, even if a cosmetic is generally recognized as safe for use and therefore excluded from the premarketing clearance provisions of H.R. 6788,—the cosmetic bill last before Congress,—"It would still be covered by the • • • Color Additive Amendments of 1960" (Tr. pp. 302-303).

[fol. 133]

E. *Compliance With the Regulations*

28. The Olick affidavit states "that plaintiffs have never sought to comply with the regulations" (Para. 4). This is simply not true. *It is only with respect to the testing, listing and certification of finished cosmetic products that plaintiffs have failed to comply with the Regulations.*

29. Promptly after enactment of the Color Additive Amendments, industry representatives had frequent meetings with FDA scientists during which they discussed and agreed upon the methods and procedures for testing the color ingredients added to cosmetic products. As noted in the affidavit of Fuller Holloway, sworn to March 24, 1964, as a result of the testing procedures agreed to with FDA, industry has "arranged with independent clinical laboratories to perform the necessary testing for approximately 25 colors to be listed for use in cosmetics" (p. 7).

Industry has submitted periodic reports to FDA on the progress of such tests, and FDA has been kept fully advised of all technical data, as developed.

30. The testing required by the Regulations, with respect to just the color ingredients, is extremely time consuming. *Accordingly, FDA has extended the closing date for listing of the color ingredients added to food, drugs and cosmetics.* However, no comparable extension has been granted with respect to the listing of lipstick, rouge, eye makeup or any other finished cosmetic product. Only after [fol. 134] this action commenced did FDA advise industry that the Regulations would not be enforced against such products, but only during the pendency of this action. FDA has never stated that such nonenforcement would continue after this action terminated were defendants to prevail. Indeed, were the Court to decide in defendants' favor, whether on jurisdictional grounds or on the merits, all finished cosmetic products which color the body or which contain a color would be subject to immediate seizure, and their manufacturers to criminal penalties.

F. *Miscellaneous*

31. Although defendants have renewed the motion previously made, their present motion is not made upon the affidavits and other documents submitted on the prior motion. This may be an oversight. In any event, it would appear proper to have before the Court the affidavits on the prior motion, so that there can be no question as to plaintiffs' right to rely upon them in the event of an appeal. Accordingly, these are incorporated herein by reference.

Wherefore, deponent respectfully prays that defendants' motion to dismiss the complaint be denied.

Edward J. Ross.

(Sworn to November 23, 1965.)

[fol. 135]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

REPLY AFFIDAVIT OF ARTHUR S. OLICK—
Dated December 1, 1965

State of New York,
County of New York, ss.:

Arthur S. Olick, being duly sworn, deposes and says:

1. I submit this affidavit in reply to the affidavit of Edward J. Ross, sworn to November 23, 1965, submitted by plaintiffs in opposition to defendants' renewed motion to dismiss the complaint and for summary judgment in their favor.

2. Mr. Ross' affidavit clearly manifests the illusory nature of the instant litigation. What the plaintiffs have done, through their counsel, is to take issue with the interpretations given the Color Regulations by various officials of the Food and Drug Administration (hereinafter called FDA). Whereas, the complaint and the answer purport to raise the question of whether or not the Color Additive regulations conform with the statute upon which they are based and which they seek to implement, this lawsuit has degenerated into an argument between the cosmetic industry and the Food and Drug Administration as to how the Regulations are to be interpreted and applied. Deponent submits that this Court is not the appropriate forum for resolving such a controversy. The statute itself, as well as the Regulations, afford ample opportunity for testing the validity of FDA's position within the context of specific cases.

[fol. 136] 3. In his affidavit Mr. Ross blatantly states that the "Parties are not in disagreement as to the meaning of the Regulations" (para. 5). With equal facility he then

goes on to state that the Regulations require "FDA clearance for substantially every cosmetic marketed today, including all hair dye products, as well as all the separate ingredients of such cosmetics" (para. 22). The Regulations, on their face, require no such thing. The final Regulations relating to color additives [28 F.R. 6439, June 22, 1963] require the pre-testing only of that limited class of cosmetics which may properly be defined as color additives within the meaning of the statute. The Regulations set forth the conditions that must be met in the marketing of cosmetics of this class. Regulations section 8.1(f) defines "Color Additives" in the very same language utilized in the statute and then goes on to give examples of *certain* finished cosmetic products which are deemed to be included in such definition. The point which must be emphasized is that the statute itself defines "Color Additives" to include specifically those substances, whether finished cosmetic products or not, that impart color to the human body. The FDA has made it clear that a cosmetic such as lipstick, rouge or eye shadow which directly or through reaction colors the human body is to be regarded as a color additive. However, it does not necessarily follow, as assumed by the plaintiffs, that every color additive which colors the human body must be individually listed. FDA has repeatedly stated its intention to prepare a list of diluents which may safely be used in these color additives. If a manufacturer then uses a straight color [fol. 137] which has been listed and suitable diluent on this diluent list, in a lipstick for example, the individual listing of the lipstick is not required. David J. Miller of FDA, described by Mr. Ross (para. 14) as the "principal draftsman of the Regulations", has so stated on numerous occasions. Unless and until the plaintiffs seek the listing or exemption of their color additives, or those finished cosmetic products which might be regarded as color additives, it is pure unadulterated speculation on their part to insist that FDA will "require pretesting, listing and certification of substantially all finished cosmetic prod-

ucts, including those generally recognized as safe . . . " (para. 6).

4. Both the statute itself and the Regulations provide ample opportunity for the plaintiffs to test FDA's intentions. There are extensive provisions for listing, certification and exemption on petition of any manufacturer. FDA is required by law to publish these petitions, to hold hearings, to secure the views of qualified experts and to subject its determinations to judicial review. This is clearly the route contemplated by the Congress and it is the route the plaintiffs should be compelled to travel.

5. Plaintiffs repeat their argument that the Regulations impose an enormous burden and cost upon them. Certainly the Congress contemplated a significant financial burden on the cosmetic industry when it specifically provided for testing of color additives, listing and certification of color additives, and fees for such listing and certification. That certain cosmetic manufacturers might find these costs [fol. 138] prohibitive is irrelevant in the context of the manifest Congressional intent to protect the public health and welfare. Moreover, any such claim is purely speculative since the plaintiffs have never sought to comply with the statute or the Regulations and do not really know just how much testing the FDA will require in any given case.

Wherefore, deponent respectfully prays that the motion be granted and the complaint dismissed.

Arthur S. Olick, Assistant United States Attorney.

(Sworn to December 1, 1965.)

[fol. 139]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

SUPPLEMENTAL AFFIDAVIT OF EDWARD J. ROSS
—Dated December 3, 1965

State of New York,
County of New York, ss.:

Edward J. Ross, being duly sworn, deposes and says:

1. I am a member of Breed, Abbott & Morgan, attorneys for all plaintiffs herein.

2. Defendants' reply memorandum, served December 1, 1965, states that "These plaintiffs * * * have made no attempt to either comply with the regulations or to secure exemption therefrom. *Not a single petition for listing,* certification or exemption has been filed" (p. 8).

The Olick affidavit, sworn to November 18, 1965, states "that plaintiffs have never sought to comply with the regulations" (para. 4). Defendants' prior memorandum states "Plaintiffs have not bothered to seek certification or listing of any of their products or components * * *. All plaintiffs need do to test the FDA's definition of a color additive, for example, is to request listing and certification of a particular dye separate and apart from the finished cosmetic product in which it is used" (p. 6).

3. The foregoing statements are not true insofar as they relate to dyes or pigments, which plaintiffs claim are the color additives intended by Congress to be listed. [fol. 140] Beginning May 12, 1965 petitions were submitted to FDA for the listing of various color additives, as follows:

Ext D&C Yellow No. 7	(CAP [Color Additive Petition] No. 26	May 12, 1965
D&C Reds No. 8 & 9	(CAP No. 28)	May 18, 1965
D&C Reds No. 10, 11, 12 & 13	(CAP No. 29)	May 18, 1965
D&C Red No. 31	(CAP No. 32)	June 30, 1965
D&C Yellows No. 7 & 8	(CAP No. 34)	July 26, 1965
D&C Orange No. 4	(CAP No. 35)	August 2, 1965
D&C Violet No. 2		September 30, 1965
D&C Red No. 34		October 22, 1965
D&C Red No. 17		November 4, 1965
D&C Reds No. 6 & 7		November 15, 1965

[fol. ~~141~~] 4. A typical letter of transmittal is as follows:

July 26, 1965

Commissioner of Food and Drugs
Food and Drug Administration
Department of Health, Education and Welfare
Washington 25, D.C.

Dear Sir:

Petitioner submits this petition pursuant to Section 706 (b)(1) of the Federal Food, Drug, and Cosmetic Act, requesting listing by the Commissioner of the color additive D&C Yellow No. 7 and related D&C Yellow No. 8 as suitable and safe for use in drugs and cosmetics that are applied externally.

Attached hereto in triplicate and constituting a part of this petition are the following:

A) The name and all pertinent information concerning D&C Yellow No. 7 and D&C Yellow No. 8 and the substances used in the manufacturing process.

B) The amount of D&C Yellow No. 7 and D&C Yellow No. 8 to be used and directions regarding the proposed use of color additives.

C) Practicable methods to determine D&C Yellow No. 7 and D&C Yellow No. 8 and other components of the color additives.

[fol. 142]

D) Full reports of investigations made with respect to the safety of D&C Yellow No. 7.

E) Date indicating the probable consumption and/or other relevant exposure to D&C Yellow No. 7 and D&C Yellow No. 8.

F) Proposed regulation governing the use of D&C Yellow No. 7 and related D&C Yellow No. 8 in externally applied drugs and cosmetics.

G) Exemption from batch certification—not requested.

H) Alteration of existing regulation—not applicable.

Listed numbers appearing in the test of the petition refer to references which will be found at the end of the petition.

A certified check payable to the order of the Food and Drug Administration in the amount of $2600 is enclosed herewith as the prescribed deposit.

Sincerely yours,

Hazelton Laboratories, Inc.
Robert A. Scala, Ph.D.
Consultant to:

The Toilet Goods Association, Inc.

[fol. 143] 5. It will be noted that the attachments to the petition set forth the information required by the Regulations, including "Full reports of investigations made with respect to the safety of D&C Yellow No. 7."

It will also be noted that each petition was accompanied by a certified check to the order of FDA, in the amount of $2,600, as the deposit required under the Regulations.

6. Petitions have been submitted with respect to 16 separate dyes. To date, no response has been received from FDA as to any of the petitions, and the petitioner is simply awaiting action by FDA.

7. None of the plaintiffs have applied for certification, as defendants state, since certification has to follow the granting of a listing application. Until the color additive is listed, an application for certification cannot be made.

Edward J. Ross

(Sworn to December 3, 1965.)

[fol. 144]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

AFFIDAVIT OF A. S. OLICK—Dated December 6, 1965

State of New York,
County of New York, ss.:

Arthur S. Olick, being duly sworn, deposes and says:

1. Plaintiffs in an affidavit to be filed with the Court on December 6, 1965, assert that they have sought to comply with the Color Additive Amendments to the Federal Food, Drug and Cosmetic Act by filing petitions for listing. Some 10 petitions have indeed been filed with the Food and Drug Administration seeking the listing of certain specific colors for external use. These were filed between May and November of 1965.

2. All 10 of these petitions are patently deficient because they do not specify the conditions of intended use for the subject colors as required by the Act. Four of the listing petitions are also deficient because they involve experimental work by a laboratory that has been disqualified by FDA. All of these facts have been orally communicated to the respective petitioners and this information comes as no surprise to them.

3. Because of the pendency of this lawsuit, these petitions have not yet been acted upon although the petitioners have been told that they are inadequate.

Arthur S. Olick, Assistant United States Attorney.

(Sworn to December 6, 1965.)

[fol. 145]

IN THE UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket No. 30261

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.; AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.; CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO., LTD.; COTY, INC.; FABERGÉ INC.; FRANCES DENNY, INC.; THE FULLER BRUSH CO.; THE GEORGE W. LUFT CO., INC.; THE GILLETTE COMPANY; A. M. HANSEN, doing business as HOUSE OF HOLLYWOOD; HARPER METHOD, INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUSTRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABORATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN & FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, doing business as STUDIO COSMETIC CO.; MAX FACTOR & CO.; MAYBELLINE CO.; MERLE NORMAN COSMETICS, INC.; JACK B. NETHERCUTT, doing business as NETHERCUTT LABORATORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS, INC.; OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.; PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORATORIES, INC.; SHULTON, INC.; and YARDLEY OF LONDON, INC.; Plaintiffs-Appellees,

against

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, Defendants-Appellants.

Appendix to Appellees' Brief—Filed February 18, 1966

[File endorsement omitted]

[fol. 147]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 63 Civ. 3349

THE TOILET GOODS ASSOCIATION, INC., *et al.*, Plaintiffs,

against

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, *et ano.*, Defendants.

AFFIDAVIT—March 25, 1964

State of Wisconsin,
Milwaukee County, ss.:

Charles R. Kircher, being first duly sworn, on oath deposes and says:

I am a chemical engineer and a vice-president and director of Kolmar Laboratories, Inc. ("Kolmar"), one of the plaintiffs in the above action. I have been associated with Kolmar for 29 years. I have studied the Color Regulations promulgated by the Food and Drug Administration (FDA), 28 F. R. 6439, and the cost to Kolmar of complying with them. This cost would be so prohibitive, it would substantially destroy Kolmar's entire domestic cosmetic business.

Kolmar has been engaged in the manufacture and sale of cosmetics for 43 years. Its finished cosmetic products are manufactured for and sold to other cosmetic companies for resale under their own labels and brand names. It is the largest such private label cosmetic manufacturer in the world. It services 397 customers in the United States, many of whom are small cosmetic companies who rely exclusively on Kolmar and other private label manufacturers [fol. 148] for supply. Kolmar makes a compete line of cosmetics, including lipstick, rouge, eye makeup, nail polish and face powder. These and other cosmetics that color the

body account for approximately 60% of its total dollar sales.

Kolmar manufactures and sells in excess of 2,700 different formulae or finished cosmetic products that color the body. All of such products come within the Color Regulations definition of a "color additive." As a result, each of these finished products must be listed, and a fee of $2,600 must accompany each listing petition. Thus, it would cost Kolmar some $7 million in fees just to list its finished cosmetic products that color the body.

While these fees are alone sufficient to drive Kolmar out of business, the Color Regulations do not stop there. They also require a separate listing for each "diluent" in a finished cosmetic product. A diluent has always been defined by chemists and others in the FDA and the cosmetic and color industries as the substance used to dilute the strength of the dye, pigment or other pure coloring substance. But the Color Regulations redefine diluent to mean substantially all the ingredients of a finished cosmetic product other than the color ingredient. Kolmar uses 264 of such non-coloring ingredients in its finished cosmetic products. By virtue of the expanded definition of a diluent, Kolmar could not use these ingredients until they have been listed. The listing fee for each such ingredient is $250.

While FDA has, on its own initiative, listed 65 of these ingredients for use in specified types of cosmetic products, Kolmar would still have to apply for listing of the remaining 199 and any of the 65 ingredients that are to be used in cosmetics not covered by the FDA listing.

It is possible that other cosmetic manufacturers will apply for and obtain listing of some of these same 199 ingredients, and this may reduce Kolmar's listing fees. [fol. 149] Another major expense is imposed by the requirement that each listing petition be supported by extensive physical and chemical tests. These tests must establish, among other things, the physical, chemical and biological properties of the ingredients sought to be listed, and other detailed data derived from animal and biological

experiments. Separate tests would be required for each of Kolmar's 2,700 finished cosmetic products. We have been notified by an independent clinical testing laboratory that the cost of performing the minimum tests for one product would be $3,000. This cost is broken down as follows:

1. Primary irritation tests with rabbits—$50.00.

2. Acute dermal toxicity tests with rabbits—$125.00.

3. Sub-acute dermal toxicity tests 90 days, 12 rabbits—$1000.00.

4. Human patch tests, 25 people under qualified dermatologist—$1800.00.

On this basis it would cost Kolmar $8,100,000.00 for minimum testing. However, FDA has advised us that such minimum tests would not be sufficient. They have indicated, for instance, that patch tests on 25 people are not significant and suggest a minimum of 200 people. This would increase the patch test costs by eight times or $14,400.00 for each finished cosmetic product. This, in turn, would increase the total testing expense from $8,100,000.00 to $42,120,000.00.

Since the Color Regulations also require listing of the non-color ingredients of a finished cosmetic product, these ingredients would also have to be pretested. The cost for the minimum testing for these ingredients would be $597,000.00. As a result of the increased testing suggested by the FDA, the cost would be $3,104,000.00.

Another major item of costs is imposed by the certification requirements of the Color Regulations. The Color Regulations impose a minimum certification fee of $100.00 [fol. 150] for each batch of color additives certified. Kolmar manufactures on the average of 150 batches of cosmetics that color the body per week. Over the period of one year certification fees for this number of batches would be $750,000.00.

The certification provision and other provisions of the Color Regulations also require detailed record keeping and

other administrative burdens that would force Kolmar to employ approximately five additional full time employees just to comply with these aspects of the Regulations.

In addition to the above described financial burdens, the Color Regulations would materially discourage Kolmar's research and scientific development work in the cosmetic field. Since the Color Regulations require a finished cosmetic product and all its ingredients to be listed, which listing would be published in the Federal Register, Kolmar would be forced to disclose the identity of many cosmetic ingredients that it has developed over a period of years at great cost. These secret ingredients would thus be made available to others who did not share in the development costs.

Charles R. Kircher

Sworn to March 25, 1964.

[fol. 151]

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

AFFIDAVIT—April 3, 1964

State of New York,
County of New York, ss.:

Dr. Samuel Zuckerman, being duly sworn, deposes and says:

1. I am a Vice President of H. Kohnstamm & Co., Inc. ("Kohnstamm"), a color manufacturer. I am a graduate chemist and have been closely connected with the production and testing of colors for 28 years. I am familiar with the Federal Food, Drug and Cosmetic Act ("Act"), the Color Additive Amendments of 1960, the Color Regulations purported to be promulgated thereunder by the Food and Drug Administration ("FDA"), and I am generally familiar with all FDA regulations concerning colors for use in or on food, drugs or cosmetics.

2. The color industry, which has annual sales of less than $10,000,000, includes, in addition to Kohnstamm, the following companies: Allied Chemical Corp.; Bates Chemical Co., Inc.; Wm. J. Strange & Co.; Sterwin Chemicals, Inc.; Warner-Jenkinson Manufacturing Co.; and Ansbacher-Siegel Corporation.

The color ingredients manufactured by these companies are purchased by food, drug or cosmetic manufacturers and are added to said articles for the purpose of imparting color thereto, or, in the case of cosmetics, to enable the article to color the body. Such color ingredient is either a dye, pigment or some other coloring substance. Dyes, which are soluble, and pigments, which are insoluble, not only impart color but are themselves colors. There are other substances which impart color but which differ from dyes and pigments in that they are themselves colorless. An example of such other substance is dihyroxy acetone, [fol. 152] used in the cosmetic product "Man-Tan". This is a clear substance that imparts a color when applied to the body.

3. There are two general categories of colors:

(i) Natural colors, which are derived from animal, vegetable or mineral; and

(ii) Synthetic colors, which are made by a process of synthesis.

The discovery of dye synthesis by Perkins in 1856 led to the production of synthetic organic colors. Synthetic organic colors were found to be generally superior to natural colors in uniformity, tinctorial value and application properties, and therefore became the most widely used color additives in food, drugs and cosmetics. The synthetic dyes and pigments most widely used as such color additives are chemical compounds which are or can be derived from coal-tar or coal-tar constituents, known as "coal-tar colors".

The first Food and Drug Act (1906) did not cover cosmetics, and did not require the listing or certification of

the color additives added to food, drug or cosmetic products. However, the Secretary of Agriculture, who administered the 1906 Act, promulgated for industry guidance a list of "coal-tar colors", with specifications, which were harmless and safe for use. The color manufacturers voluntarily submitted samples from each batch of "coal-tar colors" to the Department of Agriculture to assure compliance with the specifications.

Under the 1938 Act, color additives added to food, drug or cosmetic products were required to be listed and certified. But this requirement was limited only to the "coal-tar colors"—the natural colors were not covered by the listing and certification requirements of the 1938 Act.

Included among such natural colors are certain dyes which are not only used to color foods, drugs or cosmetics, but which themselves are food, drug or cosmetic articles. Beet juice and cottonseed flour are examples of food articles [fol. 153] that are used to color other articles. Beta carotene and riboflavine are examples of vitamins or drugs which are also used to color other products. Talc is an example of a cosmetic which is also used to color other articles.

4. A dye or pigment, in its purified state, is stronger than required for its function of imparting color to food, drug or cosmetic products. Accordingly, the dye or pigment is diluted or increased in volume by an inert substance called a "diluent". Before such dilution, the dye or pigment is called a "straight color". FDA's regulations under the 1938 Act recognized that the diluent is added to the color; it is not itself a color, and did not have to be listed. This long-standing interpretation and practice has now been abolished by the Color Regulations. The Regulations define "color additive" to include "all diluents", and define "diluent" as any compound of a color additive mixture which facilitates use of the mixture. Since every ingredient of a cosmetic product containing a color mixture facilitates use of the mixture, all such non-coloring ingredients be-

come "diluents", subject to pretesting, listing and certification.

Finished cosmetic products contain hundreds of other ingredients in addition to the straight color additive and the diluent. For example, a typical lipstick may contain, in addition to the color and diluent, the following other ingredients: Wax, Candelilla Wax, Beeswax, Carnauba Wax, Ozokenite, Ceresin, Caster Oil, Lanolin, Butyl Stearate, Lecithin, Petrolatum, Cetyl Alcohol, Fragrance, Propyl Paraben, Isoproyl Myristate and Diethyl Sebacate. These ingredients perform one or more functions for a finished lipstick product, such as to prevent running, to create an emollient effect, to reduce viscosity, and to provide a pleasant fragrance. These and hundreds of other non-coloring ingredients have been used in lipsticks and other cosmetics for many years. FDA has never before defined them as color additives or diluents, and has never required that they be listed or certified.

Samuel Zuckerman.

Sworn to April 3, 1964.

[fol. 154]

IN UNITED STATES DISTRICT COURT

U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration
Washington 25, D. C.

FOR RELEASE IN A.M. PAPERS

Saturday, June 22, 1963

The Food and Drug Administration today announced regulations for assuring the safety of color additives used in foods, drugs, and cosmetics. The regulations were published in today's Federal Register.

FDA said the regulations implement the Color Additive Amendments to the Federal Food, Drug, and Cosmetic

Act, and have taken into account comments and suggestions made in response to proposed regulations published earlier.

Commissioner of Food and Drugs George P. Larrick pointed out the following specific changes in existing procedures and interpretations which he said would strengthen consumer protection from possibly unsafe colors:

1. Additional safety precautions are provided for lipsticks, rouge, eyebrow and lash color and other substances that apply color to the human body. Under the new regulations, FDA will require that an entire product—not just the color ingredient—be shown by the manufacturer to be safe before it is released for sale.

Previously only color of the coal tar type ingredients had been subject to the requirement for pre-marketing proof of safety.

Commissioner Larrick said the new requirement is based on the language in the law and the legislative intent to insure that the entire formulation of a "color additive" is safe for the consumer.

2. The language of the regulation dealing with exemption of hair dyes from the safety clearance and certification requirement has been clarified to show that the "patch [fol. 155] test" requirement applies only to hair dyes which are dangerous because the user may be sensitive to them. Thursday, October 3, 1963

Commissioner Larrick said that the exemption in the 1938 law was conditioned on a labeling requirement calling for the use of a patch test to determine whether the user is sensitive to the color before the hair dye is applied. The patch testing requirement offers no protection from other types of toxicity, Commissioner Larrick said, and the purpose of the new regulation is to close this gap. Hair dyes that do not cause a reaction with the patch test must now be demonstrated to be safe before they can be marketed.

3. The regulations provide that FDA may refuse to certify a color additive—and thus in effect ban it from the

market—if the manufacturer refuses FDA inspectors access to manufacturing facilities, processes, and formulas involved in manufacture of the additive.

This provision does not represent a change in policy, Commissioner Larrick said, but the new regulations spell out the policy more specifically. He said that the FDA cannot determine whether the conditions for safe use of color additives, including products exempt from certification, are being met unless a complete inspection of the plant and formulas can be made.

The new regulations also outline for manufacturers the type of experimental data and other information which will be required and how to submit it to obtain safety clearance for permanent listing and setting of safe tolerances for color additives. The regulations cover such matters as definition of terms, fees to be charged for listing and certification of batches of colors, labeling requirements for colors, time schedules for acting upon petitions, protection of trade secrets, procedures for obtaining certification, or exemption from certification of batches of both coal tar and non-coal tar colors; and procedures for filing objections and requesting public hearings on regulations.

[fol. 156] Safety data which may be required under the regulations include detailed data from appropriate animal and other biological experiments; information as to chemical identity and composition and physical, chemical and biological properties; a description of tests, facilities and controls used in manufacture; data on stability, including a proposed expiration date where necessary; and, when needed, satisfactory methods for detecting and measuring the color in the products in which it would be used.

The regulations provide that a safety factor of 100 to 1 will ordinarily be used in applying animal experimentation data to man, unless use of a different factor is supported by the data submitted; and provide for taking into account any probable additive effect of the toxicity of the color with that of other related colors or with food additives or pesticides which may also be present in foods.

Where the data submitted do not establish safety for all uses of the color proposed, the new color law allows FDA to make allocations among competing needs. The regulations require the submittal of data by all interested parties before the allocations are made.

Provision is made for referral to an Advisory Committee upon request of the sponsor, where the Commissioner of Food and Drugs believes the data establish that the color additive is a cancer-producing agent which could not be permitted in any amount under the anti-cancer clause of the law. The Commissioner may upon his own initiative refer the matter to an Advisory Committee under similar circumstances. The Advisory Committee would be requested to study the data and report its conclusions and recommendations to the Commissioner within 60 days, unless an extension of time is authorized upon request of the Committee.

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[fol. 157]

IN UNITED STATES DISTRICT COURT

U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Washington, D. C. 20201

FOR RELEASE TO COSMETIC TRADE PAPERS

Thursday, October 3, 1963

FDA's recent regulation limiting the exemption for hair dyes under the Federal Food, Drug, and Cosmetic Act applies immediately only to new hair dye formulations coming on the market, Commissioner of Food and Drugs George P. Larrick said today. Products currently being marketed will not be affected until June 22, 1965, Mr. Larrick said.

The statement was made in connection with an order in today's Federal Register dropping a former definition of a hair dye in FDA's color regulations.

The deleted regulation (21 CFR 1.200) was superseded by new regulations (Section 8.1(u)) published June 22, 1963, under the Color Additives Amendments of 1960.

The "hair dye" exemption applies to hair dyes which would otherwise be banned by the Act as containing poisonous or deleterious substances, provided the products bear specified caution labeling and adequate directions for patch testing.

FDA said that the patch test does not afford protection against all types of possibly harmful ingredients of hair dyes, and the new regulation limits the exemption to products for which the patch test would be meaningful.

The deletion of the former definition clears the record to avoid possible confusion, FDA said.

[fol. 158]

IN UNITED STATES DISTRICT COURT

Section of House Report (H. R. No. 1761, 6/7/1960, pp. 8-10) Stating the Need for Color Additive Legislation.

NEED FOR LEGISLATION

The principal reasons which give rise to the need for this legislation may be summarized as follows:

1. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection, in that it does not allow the Secretary of Health, Education, and Welfare to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, the Secretary must ban the use of such a color completely, as not being "harmless," if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe. For externally applied drugs and cosmetics, the same principle applies if toxicity appears

in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use may be wholly safe.

Prior to delisting proceedings by the Department of Health, Education, and Welfare there were 19 colors listed for unrestricted use in food, drugs, and cosmetics, 69 colors listed for unrestricted use in drugs and cosmetics, and 30 colors listed for use only in externally applied drugs and cosmetics, a total of 118 straight colors listed for certification. Seven colors have been removed from the food, drug, and cosmetic list and have been relisted for external use in drugs and cosmetic colors, so that we now have 12 food, drug, and cosmetic colors, 69 unrestricted drug and cosmetic colors, and 37 drug and cosmetic colors for external use. The Department has proposed that other colors be removed from listing and certification.

The principle of allowing colors to be used under tolerance limitations was endorsed, in 1956, by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program [fol. 159] of the Food and Drug Administration, as indicated by the following excerpt from the Committee's report:

> This Committee feels compelled to indicate that certification of a compound as "harmless and suitable for use" in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified (Report of the National Academy of Sciences-National Research Council Ad Hoc Advisory Committee To Review the Food and Drug Administration's Research Program on Coal-tar Dyes, June 1956).

2. The theoretically "perfect" public health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While, theoretically, only "harmless" colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many of the so-called colors on the list

may in fact be toxic in some concentrations. Yet, the Secretary of Health, Education, and Welfare cannot take a particular color off the list until he establishes its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the established colors would have to be completed—primarily by industry—and during which the Secretary could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

3. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At pres- [fol. 160] ent there are no provisions for the certification of non-coal-tar colors. There is, moreover, no pretesting requirement for non-coal-tar color additives as such, other than food additives.

4. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting

the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by the Department of Health, Education, and Welfare.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress [fol. 161] in temporary emergency legislation (Public Law 86-2) with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring mature oranges, after previous adoption of the "safe-for-use" principle in the Food Additives Amendment of 1958 (Public Law 85-929). In reporting upon the emergency legislation for citrus red No. 2, this committee said:

> It is specifically provided that the provisions of this bill will became inoperative on August 31, 1961, or before that time if general legislation affecting coloring materials for food is enacted by the Congress. The reason for the time limit is that this is emergency legislation, which will meet the immediate needs of the citrus industry without permanently engrafting on the basic Food, Drug, and Cosmetic Act a new principle of tolerances for coal-tar colors which is not applicable to foods generally. The expiration date has been so fixed as to allow the Congress ample time to consider the application of this principle to all foods.

It is the intention of the committee as soon as feasible to study amendments to the Federal Food, Drug, and Cosmetic Act dealing with color additives generally, since the need for such legislation has been amply demonstrated to this committee (86th Cong., 1st sess., H. Rept. 88).

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

[fol. 162]

IN UNITED STATES DISTRICT COURT

Provisions of H. R. 11582 for Premarketing Clearance of Cosmetics and Repeal of Hair Dye Exemption.

87TH CONGRESS
2D SESSION

H. R. 11582

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 1962

Mr. HARRIS introduced the following bill, which was referred to the Committee on Interstate and Foreign Commerce

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A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices; and amend the Act with respect to cautionary labeling; and for other purposes.

* * * * * * * *

TITLE I—PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY

* * * * * * * *

[fol. 163]

TITLE I—PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY

NEW COSMETICS

SEC. 101. (a) Section 601, as amended, of the Federal Food, Drug, and Cosmetic Act (relating to cosmetics deemed adulterated) is further amended by adding at the end thereof the following new paragraph:

"(f) If it is unsafe within the meaning of section 605(a)."

(b) Chapter VI of such Act is amended by adding at the end thereof a new section as follows:

"SEC. 605. (a) A cosmetic shall be deemed unsafe for the purposes of section 601 (f) if—

"(1) its composition is such that such cosmetic is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of cosmetics, as having been adequately shown to be safe for its intended use and other reasonably foreseeable uses, or

"(2) its composition is such that such cosmetic, as a result of investigations to determine its safety for such a use, has become so recognized, but such cosmetic has not, otherwise than in such investigations, been so used to a material extent or for a material time,

unless an application with respect to such cosmetic has been filed pursuant to subsection (b) and there is in effect an approval of such application by the Secretary under this section, or unless such cosmetic is for investigational use and conforms to the terms of an exemption which is in effect pursuant to subsection (i).

[fol. 164] "(b) Any person may file with the Secretary an application for determination by the Secretary of the safety of any cosmetic described in clause (1) or (2) of subsection

(a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such cosmetic is safe for use; (2) a full list of the articles used as components of such cosmetic; (3) a full statement of the composition of such cosmetic; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such cosmetic; (5) such samples of such cosmetic and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such cosmetic.

* * * * * * *

REPEAL OF SPECIAL EXEMPTIONS FOR HAIR DYES

SEC. 103. (a) Paragraph (a) of section 601 of such Act is amended by striking out the colon which precedes *"Provided"* and all that follows down to but not including the period at the end of such subsection.

(b) Paragraph (e) of such section 601 is amended by striking out "it is not a hair dye and".

(c) Paragraph (e) of section 602 of such Act is amended by striking out the second sentence of such paragraph.

(d) Subsection (a) of section 706 of such Act is amended by striking out "other than a hair dye (as defined in the last sentence of section 601(a))".

[fols. 165-167]

Clerk's Note: "Order denying motion to dismiss and for summary judgment and certifying an immediate appeal" is omitted from the record here as it appears on pages 46-47 supra.

[fol. 168]

IN THE UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

THE TOILET GOODS ASSOCIATION, INC., et al., Plaintiffs,

—v.—

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, Defendants.

Before: Moore, Smith and Anderson, U.S.C.JJ.

ALLOWANCE OF MOTION FOR LEAVE TO APPEAL PURSUANT TO 28 U.S.C. §1292(b)—Filed January 10, 1966

Motion for leave to appeal pursuant to 28 U.S.C. §1292 (b) granted. Argument set for week of February 21, 1965. Notice of appeal to be filed forthwith. Parties to agree on time schedule for briefs; in the absence of agreement, parties may confer with the court with respect thereto.

LPM, JJS by LPM, RPA by LPM, U.S.C.JJ.

January 10, 1966

[fol. 169] [File endorsement omitted]

[fol. 170]

IN THE UNITED STATES COURT OF APPEALS

SECOND CIRCUIT

Present: Hon. Leonard P. Moore, Hon. J. Joseph Smith, Hon. Robert P. Anderson, Circuit Judges.

THE TOILET GOODS ASSOCIATION, INC., et al.,
Plaintiffs-Appellees,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, Defendants-Appellants.

ORDER GRANTING MOTION FOR LEAVE TO APPEAL
—January 10, 1966

A motion having been made herein by counsel for The Toilet Goods Association, Inc., et al., for leave to appeal,

Upon consideration thereof, it is

Ordered that said motion be and it hereby is granted and that the notice of appeal shall be filed forthwith.

Further ordered that the argument of the appeal be and it hereby is set for the week of February 21, 1966.

Further ordered that the parties shall agree on a time schedule for briefs or that in the absence of agreement, the parties may confer with the court with respect thereto.

A. Daniel Fusaro, Clerk.

[fol. 171] [File endorsement omitted]

[fol. 172]

IN THE UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 325—September Term, 1965.

Argued February 25, 1966

Docket No. 30261

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.; AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.; CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO., LTD.; COTY, INC.; FABERGE INC.; FRANCES DENNY, INC.; THE FULLER BRUSH CO.; THE GEORGE W. LUFT CO., INC.; THE GILLETTE COMPANY; A. M. HANSEN, doing business as HOUSE OF HOLLYWOOD; HARPER METHOD, INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUSTRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABORATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN & FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, doing business as STUDIO COSMETIC CO.; MAX FACTOR & CO.; MAYBELLINE CO.; MERLE NORMAN COSMETICS, INC.; JACK B. NETHERCUTT, doing business as NETHERCUTT LABORATORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS, INC.; OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.; PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORA-
[fol. 173] TORIES, INC.; SHULTON, INC.; and YARDLEY OF LONDON, INC., Plaintiffs-Appellees,

—v.—

JOHN W. GARDNER, Secretary of Health, Education and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, Defendants-Appellants.

Before: Waterman, Moore and Friendly, Circuit Judges.

Appeal by the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs from an order of the District Court for the Southern District of New York, Harold R. Tyler, Jr., Judge, denying their motion to dismiss or grant summary judgment in an action for a declaration of invalidity of four Food and Drug Administration regulations relating to color additives. Affirmed as to Counts 1, 2 and 3; reversed as to Count 4.

Arthur S. Olick (Robert M. Morgenthau, United States Attorney for the Southern District of New York; James G. Greilsheimer, Assistant United States Attorney, of Counsel), for Defendants-Appellants.

Edward J. Ross (Breed, Abbott & Morgan, New York, N. Y.; Stephen R. Lang, of Counsel), for Plaintiffs-Appellees.

[fol. 174]

OPINION—Decided April 13, 1966

Friendly, Circuit Judge:

In July 1960, Congress added to the Federal Food, Drug, and Cosmetic Act a number of new provisions known as the Color Additive Amendments, 74 Stat. 397, 21 U.S.C. §§321-376. These were intended

> "to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerance, under which such additives may be safely used." H. R. Rep. No. 1761, 86th Cong., 2d Sess., 1960 U. S. Code Cong. & Ad. News 2887.

The Commissioner of Food and Drugs, to whom the Secretary of Health, Education and Welfare has delegated the Department's functions under the Act, 22 F. R. 1051 (1957), 25 F. R. 8625 (1960), held rule-making proceedings conforming to §4 of the Administrative Procedure Act, 5 U. S. C. §1003, and issued Color Additive Regulations, 21

C. F. R. Part 8, effective, with certain exceptions, on June 22, 1963.

The following November the Toilet Goods Association, a trade organization of cosmetic manufacturers whose members allegedly represent 90% of annual United States sales, and forty manufacturers and distributors of cosmetics brought this action against the Secretary and the Commissioner in the District Court for the Southern District of New York for a declaratory judgment that four provisions of the Regulations exceeded the authority conferred by the statute. Jurisdiction was properly predicated on 28 U. S. C. §§1331 and 1337. See *Smith* v. *Kansas* [fol. 175] *City Title & Trust Co.*, 255 U. S. 180 (1921).[1] The defendants moved to dismiss or to strike certain portions of the complaint on various grounds, among others that the case was inappropriate for declaratory relief and that the action was an unconsented suit against the sovereign; plaintiffs cross-moved for summary judgment. In November 1964 Judge Tyler denied both motions in an opinion, 235 F. Supp. 648, relying in part on *Abbott Labs* v. *Celebrezze*, 228 F. Supp. 855 (D. Del. 1964), where the court had granted a declaratory judgment invalidating labeling regulations under the same statute. A year later, when the case was nearly ready for trial, the Secretary and the Commissioner renewed their motion to dismiss on the two grounds stated, arguing that a different conclusion on "the issue of justiciability" was called for by the Third Circuit's

[1] We thus do not reach the question whether §10 of the Administrative Procedure Act, 5 U. S. C. §1009, constitutes an affirmative grant of jurisdiction with respect to the review of federal administrative action, as the Supreme Court apparently assumed in *Rusk* v. *Cort*, 369 U. S. 367, 371-72 (1962) and we recently did in *Cappadora* v. *Celebrezze*, —— F. 2d —— (2 Cir. 1966). But see *Ove Gustavsson Contracting Co.* v. *Floete*, 278 F. 2d 912 (2 Cir.), cert. denied, 364 U. S. 894 (1960). Since 28 U. S. C. §§1336-40 do not require a jurisdictional amount, this question arises only in cases such as social security, passport and citizenship matters, where none of these sections is applicable and the jurisdictional amount required by §1331 is not met.

reversal of the *Abbott Laboratories* decision, 352 F. 2d 286 (1965),[2] and the District of Columbia Circuit's recent holding that declaratory relief was not available to challenge certain regulations adopted under the Tobacco Inspection Act, 7 U. S. C. §714(b), *Danville Tobacco Ass'n* v. *Freeman*, 351 F. 2d 832 (D. C. Cir. 1965). Judge Tyler adhered to his determination but, at the defendants' request, made the necessary certification for an application to prosecute an [fol. 176] interlocutory appeal under 28 U. S. C. §1292(b); permission to appeal was granted by a panel of this court.

I.

The first two counts of the complaint charge that the Regulations exceed the authority conferred by the statute in treating finished cosmetic products and all diluents—unpigmented materials with which colors are mixed—as "color additives" subject to various requirements for testing and administrative certification. The basic section of the Color Additive Amendments is §706 of the Act, 21 U. S. C. §376, which provides that a "color additive" shall be deemed unsafe unless it meets two conditions:[3] The additive must be covered by a "regulation," issued by the Secretary on a finding of suitability, which lists it for use either generally or under prescribed conditions; and it must either come from a batch certified for such use by the Secretary under appropriate regulations or have been exempted from the certification requirement.

The term "color additive," on which the controversy turns, is defined in §201(t)(1), as a material which

> (A) is a dye, pigment, or other substance made by a process of synthesis . . . or otherwise derived . . . from a vegetable, animal, mineral, or other source, and

---

[2] Subsequent to the argument of this appeal, certiorari was granted, 34 U. S. L. Week 3294 (March 1, 1966) (No. 824).

[3] This is subject to an exception, not here important, for color additives covered by an exemption for investigational use by qualified experts, 21 U. S. C. §§376(a)(2) and (f).

> (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.
>
> 21 U. S. C. §321(t)(1)

[fol. 177] The Regulations of the Food and Drug Administration (FDA) interpret the statutory definition of color additive as including "all diluents" and state further that

> A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." Reg. §8.1(f).

The term "diluent" is defined as:

> any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.
>
> Reg. §8.1(m)

The manufacturers admit that the coloring ingredient in a cosmetic is a "color additive" fully subject to both listing and certification requirements of §706, and that a "diluent," in what they insist is the accepted definition of an inert substance used to dilute dyes and pigments, is subject to the Secretary's power to certify additives "with safe diluents or without diluents," §706(c). They complain,

however, that the Regulations' comprehensive definition of "color additive" goes beyond the reach of the statute in imposing both listing and certification requirements on finished products—like lipstick, nail polish, etc.—and non-[fol. 178] color ingredients that were never intended to be subject to premarketing clearance, and on traditional diluents that were meant to be subject only to certification as components of dyes and pigments.

The third count of the complaint relates to provisions in the Regulations which attempt to subject hair dye products to premarketing clearance in what is alleged to be violation of the exemption recognized in the statute. The Act as passed in 1938, in defining those cosmetics that were deemed to be adulterated, contained in §601(a) an explicit exemption for hair dyes:

> This provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing.
>
> 52 Stat. 1054

The exemption was carried forward in §601(e) which declared that a cosmetic should be deemed adulterated "If it is not a hair dye and it bears or contains a coal-tar color other than one" from a certified batch. When Congress revised the statute in the 1960 Amendments, it left §601(a) as it was but modified §601(e) to read "If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe" within the meaning of §706.

The Regulations recognized the statutory exemption where proper labeling called for use of the patch test but,

armed with an expansive definition of "color additive" in [fol. 179] §8.1(f) which would on its face seem to include in a preparation for use on the hair any coloring ingredient as well as the finished product, proceeded to limit the exemption as follows:

> "The hair dye" exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the "hair dye" is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.
>
> Reg. §8(u)

The manufacturers claim that the Regulations go beyond the statute in several ways: Whereas the 1938 Act literally exempted from premarketing clearance any coal-tar hair dye complying with the statutory condition of notice and the amendments did not purport to effect any change, the Regulations grant exemption only if the color additive in the hair dye substance is one whose irritating qualities would be detected by a patch test; and, contrary to the longstanding interpretation—in effect by regulation when

[fol. 180] the amendments were adopted[4]—which applied the exemption in its full scope to dual-purpose hair products like shampoos, rinses and tints with a coal-tar coloring component, the Regulations seem to limit the exemption to the coloring ingredient itself.

Count 4 of the complaint attacks a section of the Regulations, §8.28(a)(4), which states that when it appears to the Commissioner that a person has refused to permit duly authorized employees of the FDA "free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived," he may suspend certification service to such person until adequate corrective action is taken. The first sentence of §704(a) of the Act, applicable to all goods, drugs, devices, or cosmetics subject thereto, authorizes the Secretary to inspect any "factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labelling therein"; the second sentence, dealing only with places where prescription drugs are manufactured, processed or held, provides for inspection extending "to all things therein (including records, files, papers, processes, controls, and facilities)." The manufacturers say the challenged regulation illegally extends to cosmetics the broadened inspection authorized only for prescription drugs, and improperly subjects trade secrets to exposure.

The expanded definition of "color additives," the narrowing of the hair dye exemption and the allegedly compelled disclosure of secret formulae and processes impose, the [fol. 181] manufacturers claim, burdens not contemplated by the statute and threaten immediate and irreparable injury. Even though coloring ingredients have been prop-

[4] Reg. §1.200 apparently defined the term "coal-tar hair dye" in the §601(a) exemption to include "all articles containing any coal-tar color." This definition of hair dyes was deleted by the Commissioner as superseded by §8.1(u) of the Color Additive Regulations. 28 F. R. 10638 (1963).

erly pretested, listed and certified in compliance with the statutory clearance scheme, the regulations require filing a separate listing application for each finished product, traditional diluent and non-color ingredient, including those formerly exempted under the hair dye provision; each application must be accompanied by a $2600 filing fee, Reg. §8.50(c), and supported by extensive scientific tests establishing suitability for intended use, Reg. §3.4(c). Even after listing, every ingredient and finished product must come from a certified batch unless the Secretary has granted an exemption; a minimum fee of $100 is charged for each certification, Reg. §8.51(a). An affidavit by one manufacturer claimed that the listing of its finished products alone for the issuance of regulations would entail filing fees of $7,000,000 and testing costs of nearly $42,000,000, and that certification fees for a single year would amount to $750,000.[5] Beyond such out-of-pocket costs, increased by substantial additional expenses for record-keeping compliance with the challenged regulations, by requiring significant changes in established business practices and curtailing distribution of new products, allegedly would cause major and costly disruption of the cosmetic industry. Moreover, the disclosure of formulae and processes necessary to meet the new listing requirements and to avoid loss of certification for refusing inspection allegedly would result in misappropriation of trade secrets and discourage research and development of improved cosmetic products.

[fol. 182] Failure to comply with the challenged regulations could have serious consequences if they are valid. Under §601 of the Act, a cosmetic other than a hair dye is deemed adulterated if "it is, or it bears or contains, a color additive which is unsafe" within the meaning of §706(a). Projection of any adulterated article into the stream of

[5] Very likely these figures are exaggerated since they take no account either of the FDA's power to require information on diluents as a condition of approving coloring ingredients and granting certification or of the likelihood of exemption from certification.

interstate commerce and refusal to allow inspection required by §704 are prohibited acts under the statute, and are subject to injunction and entail criminal liability, §§301-303; and any adulterated article may be seized under §304. The manufacturers say that, apart from all else, the publicity incident to criminal or civil proceedings against them for failure to comply with the Regulations would be seriously detrimental in a highly competitive industry which spends millions in cultivating public good will and is dependent on consumer confidence in the integrity of its products.

The Secretary and the Commissioner respond that the fears as to the dilemma posed by the Regulations are exaggerated. They insist that the Regulations merely expound the manner in which they intend to construe the amendments, that nothing has yet been done to apply the provisions of which plaintiffs complain, and that ample opportunity to test the Regulations in concrete fact situations is afforded by the path for review spelled out in the statute. If the manufacturers will only comply with the listing and certification requirements, the FDA's application of the statute will, under §706(d), be subject to the general administrative provisions on hearings and review in §701. Since the review authorized in §706(d) is directed at decisions approving or disapproving listing and certification and §§701(e) and (f) are limited to review of other specifically enumerated agency determinations, the contention is not that the statutory provisions afford a direct path to [fol. 183] review of the general regulations on listing requirements; it is rather that they furnish an indirect but nevertheless sufficient one which the manufacturers ought to have taken. The proper course, defendants say, is for a manufacturer to petition for the listing of diluents and finished cosmetic products as color additives, while protesting against the need for doing so and conforming with the detailed requirements for filing information only to the extent he believes proper under the statute; such a

petition could be accompanied by a request for exemption from batch certification, again with appropriate protest and non-compliance with the requirement of factual data to support the application. Either the FDA would retreat from applying its announced interpretation of the statute and grant the petition and the request for exemption, or it would deny them in which event the road to a court of appeals would be open under §§701(e) and (f).

II.

The serious questions[6] are whether direct challenge of the Regulations by suit in a district court is impliedly barred by the availability of review of listing and certification denials in a court of appeals, and whether the controversy is appropriate for judicial determination prior to application of the Regulations in a particular factual situation.

[fol. 184] We are not persuaded that by providing a procedure for review of certain administrative decisions under the Food and Drug Act in the courts of appeals, Congress meant to foreclose relief with respect to other agency action under the Administrative Procedure Act §10, 5 U. S. C. §1009, or the Declaratory Judgment Act, 28 U. S. C. §2201, in a case where this would otherwise be appropriate. The agency determinations specifically reviewable under §701(e) relate to such technical subjects as chemical properties of particular products and the formulation and application of safety standards for pro-

[6] We need not discuss in the text the surprising contention that an action for a declaration that federal regulatory officers have acted in excess of their authority constitutes an unconsented suit against the United States. The contrary is clearly established by *Philadelphia Co.* v. *Stimson*, 223 U. S. 605, 619-20 (1912), see *Stark* v. *Wickard*, 321 U. S. 288, 290 (1944), and indeed follows inevitably from *Ex parte Young*, 209 U. S. 123 (1908); law officers of the Government ought not to take the time of busy judges or of opposing parties by advancing an argument so plainly foreclosed by Supreme Court decisions.

tecting public health; Congress naturally did not wish courts to consider such matters without the benefit of the agency's views after an evidentiary hearing before it. Section 701, however, also contemplated other less specialized administrative action by authorizing, in subsection (a), the making of regulations for the efficient enforcement of the statute, and it expressly declared in subsection (f) that the provision for review of certain orders in the courts of appeals was "in addition to and not in substitution for any other remedies provided by law." 21 U. S. C. §371(f)(6). The section as a whole does not indicate to us any congressional intent either to insulate administrative action not covered by subsection (e) from challenge as in excess of statutory authority, see *Stark* v. *Wickard*, 321 U. S. 288, 308-11 (1944); cf. *Cappadora* v. *Celebrezze*, 356 F. 2d 1, 5 (2 Cir. 1966), or to postpone immediate challenge to such action where awaiting the issuance of adjudicative orders subject to statutory review would provide less effective relief.[7] Insofar as *Abbott* [fol. 185] *Labs.* v. *Celebrezze*, 352 F. 2d 286, 289 (3 Cir. 1965), cert. granted, intimates otherwise, we are unwilling to follow it.

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[7] The legislative history of the 1938 Act suggests that Congress had no intention of limiting review of other action by adopting a special procedure for the enumerated determinations. The House Report, referring to the savings clause in §701(f)(6), stated:

> There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.
>
> H. R. Rep. No. 2139, 75th Cong., 3d Sess., p. 11 (April 14, 1938).

The accompanying minority report, in endorsing the Secretary's challenge to the new review provisions as jeopardizing enforcement of the statute, indicated that the special procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency. H. R. Rep. 2139, Pt. 2 (April 21, 1938).

The question whether a plaintiff may obtain judicial relief in cases like this has been variously phrased as whether he has "standing" to challenge the administrative action as a person "suffering legal wrong" or "aggrieved" within the meaning of §10 of the APA, whether the dispute is an "actual controversy" within the Declaratory Judgment Act, or whether it is sufficiently "ripe" for resolution by the courts. See Jaffe, Judicial Control of Administrative Action 395-98 (1965). In fact, the critical issue is apt to be less a matter of standing or of actual controversy than of the advisability of reviewing an administrative rule prior to its application in a specific factual situation. The current healthy trend toward implementing agency policy by rule-making cuts both ways with respect to declaratory relief—increasing the need for this sort of assistance on the part of those subjected to such rules, see *Columbia Broadcasting Sys., Inc.* v. *United States*, 316 U. S. 407, 421 (1942), but also creating a danger that, unless the courts are circumspect, administration may be improperly halted, at least temporarily, before it has gotten the slightest start.[8] The problem is not to be solved, as the [fol. 186] parties suggest, by applying some readily procurable litmus paper which will determine whether a controversy is "justiciable"; what is required, as in the case of challenge to the constitutionality of a statute, is a reasoned evaluation of "both the appropriateness of the issues for decision by courts and the hardship of denying judicial relief." *Joint Anti-Fascist Refugee Comm.* v. *McGrath*, 341 U. S. 123, 156 (1951) (Frankfurter, *J.*, concurring); see Jaffe, *supra*, at 396, 423.

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[8] The danger of unwarranted postponement of the effectiveness of agency action is augmented by the fact that a suit for declaratory relief must be brought in a district court, twice removed from the supreme tribunal, whereas adjudicative orders are generally reviewable either in courts of appeals or in specially constituted district courts from which appeal lies directly to the Supreme Court. Yet here too there is another side; a district court may be in a better position than a court of appeals to carry out fact finding, as Congress recognized in the Hobbs Act, 5 U. S. C. §1037(b).

The appropriateness of passing judgment on the validity of an administrative regulation prior to its application to particular facts depends on such factors as how far the rule represents the definitive position of the agency and the extent to which the challenge raises a clearcut legal issue susceptible of judicial solution without reference to fact variables arising in its implementation. Cf. *Northeast Airlines, Inc.* v. *CAB,* 345 F. 2d 662, 664 (1 Cir. 1965). Review might be considered premature where an agency rule had not received substantially as full consideration in its formulation as it would have in subsequent application, or where future experience would be likely to result in significant modifications as to its precision or scope. Judicial determination might also be deemed inappropriate where the controversy over the rule did not present a legal issue that a court was qualified to resolve without reference to factual determinations more effectively made by the agency familiar with day to day administration. See Jaffe, *supra,* at 406. In this case, however, the Regulations under [fol. 187] attack were issued after a full hearing with notice and by their terms represent the definitive agency position on the reach of the statutory requirements for listing and certification of cosmetics; see *Columbia Broadcasting Sys., Inc.* v. *United States, supra,* 316 U. S. at 422; *United States* v. *Storer Broadcasting Co.,* 351 U. S. 192, 198 (1956); to the extent that they purport to apply premarketing requirements to broad categories like finished products and noncoloring ingredients and define the hair-dye exemption, they appear, *prima facie,* to be susceptible of reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency. Indeed, it is manifest that if the manufacturers adhere to their legal position, *pro forma* individual applications to the FDA for listing and certification would produce a record no more, and very likely less, illuminating than what the district court will develop at trial of this action in which the great bulk of the industry is represented and will be bound. The mere

fact that the procedure which the defendants suggest would bring the issue directly to a court of appeals without prior resort to a district court, while entitled to some weight, is not controlling. As indicated earlier, the statutory procedure for review of individual determinations in the courts of appeals was not intended as a means for challenging FDA rule-making of the usual sort; as shown by the authorities discussed below, the mere fact that pursuit of that course could produce a decision on legal issues similar to that here sought does not make its use mandatory.

With respect to the other relevant consideration, the degree of hardship warranting declaratory relief, although some older precedents suggest broadly that an administrative ruling is not reviewable until and unless it imposes an [fol. 188] obligation or subjects the plaintiff to some civil or criminal liability, see, e.g., *United States* v. *Los Angeles & Salt Lake R.R.*, 273 U. S. 299, 309-10 (1927); *Shannahan* v. *United States*, 303 U. S. 596, 599 (1938), there has been a growing recognition that the timeliness of review depends on a broader concept of the substantiality of present or immediate harm. See 3 Davis, Administrative Law Treatise §2107 (1958). In *Columbia Broadcasting Sys., Inc.* v. *United States*, 316 U. S. 407, 417-21 (1942), the Supreme Court declared that though a particular rule does not of itself deny a license or directly impose sanctions, it may nevertheless be reviewable if it establishes a general standard of conduct which by its very promulgation demands conformity and poses, for the plaintiff or others with whom he must deal, the alternatives of compliance or severe penalties of forfeiture or disruption of business operations. In *Frozen Food Express* v. *United States*, 351 U. S. 40, 43-44 (1956), the Court recognized that an agency order generally announcing the scope of administrative regulation was subject to immediate frontal attack, although opportunities for later challenge were sure to come from a cease and desist order by the ICC, see *Eastern Texas Motor Lines* v. *Frozen Food Express*, 351 U. S. 49 (1956),

or suit for an injunction by the agency or competitors.[9] And in *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192, 199-200 (1956), declaratory rules setting limits on the number of licenses to be granted for broadcasting stations under common ownership were held to be immediately reviewable because they operated "to control the business affairs" of the plaintiff and made it impossible to "cogently plan its present or future operations" so long as their [fol. 189] validity remained undetermined; direct challenge to the regulations was permitted even though review might have been obtained by provoking an adverse administrative order, see 351 U. S. at 208 (dissenting opinion).[10] See also *Flemming* v. *Florida Citrus Exch.*, 358 U. S. 153, 168 (1958).

We see little profit in debating the point, much discussed by the parties, whether the Regulations are "interpretative" or "legislative." Although that issue would have to be faced if the FDA had failed to comply with the rule-making procedures of §4 of the APA because of a claim

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[9] If it be said that the carrier was subject to liability for criminal penalties even before a cease and desist order, or an injunction, the same is true here.

[10] In fact the FCC dismissed the plaintiff's application for an additional station on the basis of the new rules the very day they were adopted, 351 U. S. at 197, but review of the particular decision was not sought.

We recognize that in *Storer* review of the rule was in the Court of Appeals for the District of Columbia, the same tribunal to which Storer would have gone for review of the denial of an application; but the dissenters thought the rationale of the majority would support a suit for declaratory relief in a district court after the 60-day limitation for seeking review by the Court of Appeals had expired, 351 U. S. at 210 (dissenting opinion of Harlan, *J.*). A more important differentiating consideration may be that awaiting denial of a future application may not have afforded a broadcaster who had reached the ceiling so full an opportunity for challenge as might appear at first blush; if the application was a competitive one for a new license, the FCC might predicate denial on other grounds, and to negotiate a transfer of an existing license in the teeth of the multiple-ownership rules would be of dubious business practicability. However, this ground for distinguishing *Storer* would not apply to *Frozen Food Express*.

on its part that the Regulations were merely "interpretative," the interpretative character of a regulation does not necessarily make it unripe for review; we perceive no reason why a rule whereby an agency subjects to regulation activities contended to be immune should be exempt from immediate review because it purports to interpret a statute although it would not be if made in the exercise, contended to be illegal, of a substantive rule-making power. See *Frozen Food Express* v. *United States, supra;* Jaffe, Ju- [fol. 190] dicial Control of Administrative Action 405-07 (1965); and 1 Davis, Administrative Law Treatise §5.03 (1965 Pocket Part), criticizing on this ground *American President Lines, Ltd.* v. *FMC,* 316 F. 2d 419 (D. C. Cir. 1963), on which defendants rely. Neither do we think anything is to be gained by an attempt at comprehensive review of the decisions; the many cases in this area are not truly reconcilable and the law has been moving in the direction of greater freedom of review, see Jaffe, *supra,* at 412-17 (which, *inter alia,* criticizes another decision relied on by defendant, *Helco Prods. Co.* v. *McNutt,* 137 F. 2d 681 (D. C. Cir. 1943)), and 3 Davis, Administrative Law Treatise §§21.06-21.08 (1958). We limit ourselves to the two recent Court of Appeals decisions which defendants most strongly urge upon us.

Danville Tobacco Ass'n v. *Freeman,* 351 F. 2d 832 (D. C. Cir. 1965), was a rather weak case for declaratory relief. The plaintiffs there were neither threatened with penalties nor, like those in *Frozen Food* and here, faced with the need of applying for licenses to permit continuation of an established business; moreover, there was no showing that the challenged regulation was in fact preventing expansion of their operations, since they had filed no applications and petitions by other applicants had been denied on grounds other than those attacked. Agreeing with the defendants that *Abbott Labs.* v. *Celebrezze,* 352 F. 2d 286 (3 Cir. 1965), cert. granted, is not distinguishable on any satisfying basis, we must confess, with all respect, our inability to understand why the plaintiffs there should be required to violate

the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief. Insofar as the *Abbott* decision rested on a negative implication from the limited review provisions of [fol. 191] the Food and Drug Act, we have already noted our inability to agree.

III.

In applying the general considerations thus developed to the precise issues here presented, we must bear in mind that this appeal is not from a declaratory judgment but from the denial of a motion to dismiss a complaint seeking one. The issue on such an appeal is not whether the grant of a declaratory judgment was in fact appropriate but whether it so clearly would not be that dismissal *in limine* was required.

As regards the counts of the complaint challenging the inclusion of finished products and color additives and the alleged restrictions of the hair-dye exemption, the appeal must fail. These Regulations appear to have an immediate impact on the industry, posing the unacceptable alternatives of complying or of incurring possible forfeitures and criminal liability, and calling into question long standing practices of premarketing testing and clearance. The issues framed by the counts of the complaint addressed to these Regulations appear sufficiently suitable for immediate judicial resolution and the threatened harm sufficiently great, that the district court properly declined to dismiss them. If the court should find that the issues are not susceptible of resolution without detailed factual evidence that ought to be first sifted by the agency, or that measures being taken by the FDA for the listing and exemption from certification of approved diluents have so reduced the hardship on the plaintiffs as to make declaratory relief inappropriate, it need not proceed to judgment. But, so far as we can now see, the sooner the industry's claims as to the coverage of the Act in these respects are determined, the better for everybody. As said in Jaffe, Judicial Review of

[fol. 192] Administrative Action 404 (1965), "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan or not to plan his operation." Moreover, the party disappointed by court decision may wish to take the case to Congress.

The fourth count of the complaint, relating to agency inspection of formulae and processes, stands differently. Here the challenged regulation, §8.28(a)(4), does not of itself demand compliance at the expense of penalties. A manufacturer who refuses access to his trade secrets is not threatened with criminal liability or seizure; the regulation does not suggest that such refusal will be deemed a "prohibited act" under the statute, as it would be in the case of prescription drugs. It simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification. Moreover, the next paragraph, §8.28(b), says that upon receipt of notice of suspension, the person so notified may request a hearing upon the factual basis therefor. If after such hearing the Commissioner should adhere to his refusal to certify, review by a court of appeals would seem available under §§706(d) and 701(f); if not, an action could be brought in the district court.

In this instance the possibility of unlawful injury to the plaintiffs is, on its face, too remote for declaratory relief. No one can now say whether the Commissioner will ever make a demand for free access to color additive processes or formulae, whether any manufacturer will ever decline this, what the Commissioner would do if so refused, and what result a hearing would have. The fact that the Commissioner's proclamation of the possible consequences of refusal may induce manufacturers to be more compliant [fol. 193] than if he had kept silent until an episode calling for action arose is not a sufficient basis for declaratory relief. Moreover, it is impossible to see what declaration a court could properly make. No one could reasonably assert that circumstances warranting suspension of certification if a manufacturer refused to give the FDA information

concerning processes or formulae could never arise; Congress' failure to empower the agency to compel an inspection of processes or formulae is not a mandate to grant certificates when the public cannot properly be protected otherwise. Review of this Regulation should be on a case by case basis and with a factual record to assist in determining whether access to secret processes and formulae is necessary and appropriate to performance of the task of effective premarketing clearance in a particular instance—at least in the absence of experience showing consistent abusive tactics.

The judgment with respect to Count 4 is reversed with instructions to grant the motion to dismiss; the judgment with respect to Counts 1, 2 and 3 is affirmed, with further proceedings to be promptly taken in the district court in accordance with this opinion.

[fol. 194]

IN THE UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Present: Hon. Sterry R. Waterman, Hon. Leonard P. Moore, Hon. Henry J. Friendly, Circuit Judges.

THE TOILET GOODS ASSOCIATION, INC., et al.,
Plaintiffs-Appellees,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, Defendants-Appellants.

JUDGMENT—April 13, 1966

Appeal from the United States District Court for the Southern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the Southern District of New York, and was argued by counsel.

On Consideration Whereof, it is now hereby ordered, adjudged, and decreed that the order of said District Court be and it hereby is affirmed as to the First, Second and Third Counts of the complaint.

It is further ordered that the order of said District Court be and it hereby is reversed as to the Fourth Count of the complaint with instructions to grant the motion to dismiss in accordance with the opinion of this court.

A. Daniel Fusaro, Clerk.

[fol. 195] [File endorsement omitted]

[fol. 196] Clerk's Certificate to foregoing transcript (omitted in printing).

[fol. 197]

SUPREME COURT OF THE UNITED STATES

No. ..... —October Term, 1966

SECRETARY OF HEALTH, EDUCATION AND WELFARE, et al., Petitioners,

vs.

TOILET GOODS ASSOCIATION, INC., et al.

ORDER EXTENDING TIME TO FILE PETITION FOR WRIT OF CERTIORARI—July 7, 1966

Upon Consideration of the application of counsel for petitioner(s),

It Is Ordered that the time for filing a petition for writ of certiorari in the above-entitled cause be, and the same is hereby, extended to and including August 11, 1966.

Potter Stewart, Associate Justice of the Supreme Court of the United States.

Dated this 7th day of July, 1966.

[fol. 198]

SUPREME COURT OF THE UNITED STATES

No. 336—October Term, 1966

THE TOILET GOODS ASSOCIATION, INC., et al., Petitioners,

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare, et al.

ORDER ALLOWING CERTIORARI—October 10, 1966

The petition herein for a writ of certiorari to the United States Court of Appeals for the Second Circuit is granted, and set for oral argument immediately following No. 39. The case is consolidated with No. 438 and a total of one hour is allotted for oral argument.

And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

Mr. Justice Brennan took no part in the consideration or decision of this petition.

[fol. 199]

SUPREME COURT OF THE UNITED STATES

No. 438—October Term, 1966

JOHN W. GARDNER, Secretary of Health, Education, and Welfare, et al., Petitioners,

v.

THE TOILET GOODS ASSOCIATION, INC., et al.

ORDER ALLOWING CERTIORARI—October 10, 1966

The petition herein for a writ of certiorari to the United States Court of Appeals for the Second Circuit is granted, set for oral argument immediately following No. 39. The case is consolidated with No. 336 and a total of one hour is allotted for oral argument.

And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

Mr. Justice Brennan took no part in the consideration or decision of this petition.